UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	May 24, 2018
Doris Jones, an individual, Plaintiff,	12:55 p.m.
	CV 16-00782-PHX-DGC
vs.	
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(Jury Trial - Day 7 - P.M. Session)
(*Pages 1484 through 1621, inclusive.*)

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I N D E X

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DONNA-BEA TILLMAN (Resumed)				
By Mr. Lopez		1500		
CLEMENT GRASSI, M.D.				
By Mr. Rogers	1512		1567	
By Mr. Clark		1546		
ANDRZEJ CHANDUSZKO				
By Ms. Helm	1568			
By Mr. Stoller		1610		

INDEX OF EXHIBITS

EXHIBIT		RECEIVED
696	GAO Dated 6-18-19 Regarding FDA	1507
5037	ETR-05-02-02 (Effects of Changes to the Recovery Filter & The Femoral Delivery System on Filter Stresses Based on FEA Analysis)	1601
5233	RD-SOP-054.00 (Recovery Filter EnduraTEC Fatigue Testing SOP NMT)	1582
5234	RD-RPT-099 (Recovery Filter EnduraTEC Fatigue Testing Report NMT)	1584
6842	ACR-SIR-SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism. Revised 2016.	1558
7312	SIR Guidelines for IVC filters	1526

P R O C E E D I N G S

THE COURT: All right, counsel. Let me share with you my thoughts after having looked at this issue over the lunch break. And then I'm going to invite your focused responses. This is a topic we could talk about forever, and we don't have time to do that. So I'm going to ask you some fairly focused questions. 12:55PM

I went back and re-read the transcript on the exchange between Mr. North and the witness about the recovery filter complications and the Dear Doctor letters. And the following points were made to the jury through that testimony. These are my words, but I think they quite closely parallel what the evidence was. 12:55PM

Bard communicated with the FDA about the performance of the Recovery Filter. Bard sent letters to doctors about complications with the Recovery Filter. Minutes of the meeting reflect that Bard told the FDA what it was seeing with the Recovery Filter in its postmarket marketing and that it planned to send a letter. And this would be based on information it had in the postmarket setting. The FDA reviewed Bard's Recovery performance information. The FDA was aware of the adverse event data regarding Recovery Filter. 12:55PM 12:56PM

The FDA independently tracked that data through the MAUDE database. The FDA reviewed the proposed letter to the doctors, made suggestions, the suggestions were accepted by 12:56PM

Bard, and the letters were sent to the doctors.

I think there are two points to distill this down that were made to the jury. One is that the FDA knew everything Bard knew about the Recovery Filter complications and approved Bard's communications to doctors about those complications. 12:56PM And the second, I think, is the implication which is Bard told the doctors everything it should have about the Recovery Filter complications. I believe that's the fair import of the evidence.

Those two points, those two summary points, I believe 12:57PM the plaintiffs are entitled to rebut if they have evidence they believe shows that the FDA did not know everything Bard knew about Recovery Filter complications. They are entitled to bring that out. And they are entitled, through this same line of evidence, that is, the Dear Doctor letters, to rebut the 12:57PM idea that Bard told the doctors everything it should have told them about the Recovery Filter complications.

Now, here's where it gets difficult. Putting context, this is one point, or collection of points, among many that have been made through this witness and hundreds that have been 12:57PM made during the trial. But it's a point that the plaintiff fairly should be permitted to rebut.

I have been wrestling with the question of what the plaintiffs should be able to do to rebut it. Clearly, to the extent the plaintiff can present non-death information about 12:58PM

complications in the Recovery that the FDA did not know about or that were not accurately described in the Dear Doctor letter, that's fair game. The question is what should the plaintiffs be permitted to do with death evidence related to the Recovery Filter. And I'm struggling with that. My concern is if we step onto that slippery slope, that could take a lot of time. It could take a lot of evidence. I know the parties could argue for hours about what evidence was or was not shared with the FDA on death evidence; what it means; how it should be interpreted. We don't have time in this trial to do that nor would that be proportional in my view to the issue that's been raised. 12:58PM 12:58PM

But I believe by interjecting into the trial this point that the FDA knew everything Bard knew and approved the communication to the doctors, the door has been opened to rebutting that. 12:59PM

So frankly, I don't know the right answer as to how far into this road we should go with death evidence to permit plaintiff fairly to rebut it. That's what I want your thoughts on. I don't want 10-minute arguments from both of you. I want focused, precise thoughts so I can consider what you have to say and make a decision on this. 12:59PM

MR. LOPEZ: I must say I share the same sentiment, Your Honor, about the time, especially with how little time we have left. But I also know that it's important that we have an 12:59PM

opportunity to fairly rebut all those things that you listed. I was going to go into some of that with her.

I can tell you --

THE COURT: Go ahead.

MR. LOPEZ: I can tell you that I don't plan to all of a sudden bring out 20 documents. I think that we should at least have an opportunity to show the fatality, statistically significant differences in fatalities done by Natalie Wong. She actually did a statistical analysis of the fatalities. But we ought to at least be able to bring in the HHE, which wasn't a statistical analysis. I think Josh had -- I think we made a list of about four or five documents. 12:59PM 01:00PM

And that we somehow or another should be able to rebut the fact that in the letter it's not mostly bariatric patients. That was a small percentage, really, of the deaths caused by the Recovery Filter. And I think that might actually be in that HHE. 01:00PM

There's also an executive summary sent to the CEO and COO that tracks the differences in the deaths and fractures between the Recovery Filter, the Simon Nitinol Filter, and other filters. 01:01PM

THE COURT: Let me interrupt you, Mr. Lopez. I understand what are you saying is that there are a few documents you think you should be able to present to this witness. Give me -- let's say you put the Wong statistic in 01:01PM

front of her. What is it you want to ask her that gets to these issues that I have outlined?

MR. LOPEZ: Whether or not that's the kind of information -- she's going to tell me that the company is responsible for doing the tracking and trending, not FDA. Once they get to a point when they realize that there's a statistically significant difference between the predicate device and the device that's cleared through 510(k), especially with something as clinically significant as deaths, I'm hoping she would say they need to bring that to the attention of FDA and maybe even stop selling it at that point because it's adulterated. 01:01PM 01:02PM

THE COURT: But see, here's my concern: What you are allowed to rebut is the suggestion they have made that the FDA knew everything and approved the doctor's communications. Getting into adulterated and things like that is other points you wanted to make through the death evidence. But I'm focused on how you should be fairly be permitted to rebut what has been presented to the jury. 01:02PM

So let me ask this question. Let's say you put the Wong evidence in front of you. Are you going to ask her, did you see this? Do you know if the FDA knew about this? If she says yes, I saw it, and yes, I believe the FDA knew about it -- 01:02PM

MR. LOPEZ: Okay.

THE COURT: -- then where are we? 01:02PM

MR. LOPEZ: Then --

THE COURT: And if she says no, and they should have been told you have made your point. But if she says yes, I saw this, and yes, the FDA knew about it, then do you want to go into more? I'm trying to figure out how we cabin this and keep it proportional to the door that's been opened. 01:03PM

MR. LOPEZ: First of all, I hope she doesn't get to say, yeah, the FDA knew about this because I don't know how she would know that unless she has something that was actually shared with them through some document. So I hope she's not going to be allowed to say, oh, yeah, the FDA knew about this. 01:03PM

THE COURT: What if she says I assume they did?

MR. LOPEZ: I would ask her to show me the evidence that she has that makes her assume that. I could get into a back and forth with her about that, about why you would assume that because that's what a responsible company would do. But you don't know that that was shared. In fact, when she says that the FDA independently tracked this, there's no evidence of that happened. 01:03PM

THE COURT: Let's stay on point here. 01:03PM

MR. LOPEZ: Okay.

THE COURT: So you want to put in a handful of documents that reflect death rates in the Recovery Filter.

MR. LOPEZ: Then we have the hold where the company says, we have a death, and we're going to put it on hold. If 01:04PM

we have one more death, if we have another -- if we have a hospitalization from this happening, we're going to continue the hold. Well, they have a death and they don't take the hold down, they don't tell the FDA that they have done this.

THE COURT: So you want to go into that, too? 01:04PM

MR. LOPEZ: I do.

THE COURT: Here's my concern: We start taking steps in and they are going to want to respond to it all. I could see us spending an hour or two on this issue of what the FDA knew about death evidence. I don't think we should do that. 01:04PM That's what I'm wrestling with in the back room is you want to make a point, they will want to make a point. You will want to make a further point and they will. And we'll lose -- we will present the 403 problem of this taking time it shouldn't be taking. 01:04PM

MR. LOPEZ: At the very least, Your Honor, I think the Natalie Wong data, the December HHE data, and the statistically significant analysis done by their consultant and probably the data that's in the executive summary that's, I think, in August of 2005, which was about two months before the Dear Doctor 01:05PM letter would probably satisfy, you know, us being able to show that the Dear Doctor letter does not really tell doctors what they need to know about Recovery.

THE COURT: Would you intend to put the letter in evidence? 01:05PM

MR. LOPEZ: Yes.

THE COURT: Traci, will you tell the jury we're taking a few extra minutes? Will you do that, please?

Okay. Have you covered the points you want to make?

MR. LOPEZ: Yes, Your Honor. 01:05PM

THE COURT: Mr. North.

MR. NORTH: Your Honor, I think the problem with what the plaintiff is proposing is it really is a slippery slope to that extent. With the exception of the Natalie Wong report, every other document that he discussed postdates the date of 01:06PM their review of this Dear Doctor letter. So how can that really rebut the point that we didn't share everything with the FDA when the HHE, for example, was done after these communications took place. This report to management took place after that communication took place. 01:06PM

We respectfully disagree with the Court's conclusion that we have opened the door, but now that the Court has made that conclusion, we think they should be extremely limited in what they can produce or confront this witness with. Maybe the Natalie Wong analysis, because that was May of 2004 beforehand. 01:06PM If they do present the Dear Colleague and Dear Doctor letter, in response we're going to go into two different FDA communications that show at this time the FDA knew of between 7 and 12 deaths. So we'll want to get that in in rebuttal to that. 01:07PM

So even just putting in the Wong memo is going to open the door for us to need to put in more evidence as to what the FDA knew.

THE COURT: So if they put in the Wong memo, you want to put in exhibits that show the FDA's knowledge of, you said, 7 to 12 deaths? 01:07PM

MR. NORTH: Yes. One of the exhibits is already in, but it was subject to redaction.

THE COURT: Okay. Did you have other points to make, Mr. North? 01:07PM

MR. NORTH: No. That's it.

THE COURT: Let me ask this question, counsel. I mean, I just am concerned about heading down the road. We could go that far. I could say these are the one or two or three documents plaintiff can put in, this is what defendants can do, and we're stopping and not going any farther. That would be one approach. 01:07PM

There's another alternative. And the other alternative would be for me to instruct the jury to disregard all of this witness's evidence about the FDA communicating with them about Recovery Filter complications. 01:08PM

Mr. O'Connor, please don't talk to counsel when I'm talking.

MR. O'CONNOR: I apologize.

THE COURT: This is about the sixth time. He needs to 01:08PM

hear what I'm saying so he can respond.

MR. O'CONNOR: I apologize.

THE COURT: Apology accepted.

Another alternative is to give a limiting instruction and I would be detailed. I would say you should disregard the evidence about the communications between Bard and the FDA regarding Recovery Filter complications, regarding the Dear Doctor letter, regarding the FDA proposing language on the Dear Doctor letter, regarding the FDA independently tracking this data. You should disregard that. That's another alternative. I'm interested in both sides' thoughts on -- that certainly saves more time, but it's an alternative. 01:08PM 01:08PM

MR. LOPEZ: Can I --

THE COURT: Now have at it.

MR. LOPEZ: I was going to yell at him too, Judge. 01:09PM

THE COURT: I don't think I yelled.

MR. LOPEZ: I didn't mean that. Reprimand.

THE COURT: I know it sounded like it.

(Discussion off the record between plaintiff's counsel.) 01:10PM

MR. LOPEZ: Well, it's like three straws, which one we're going to -- part of me says you can't unring the bell, but a part of me also wants to get the trial, you know, where we don't get all of a sudden, you know, how much is enough. And my preference would be to get -- for you to allow us a 01:10PM

limited amount to get the evidence -- some of this evidence in. Because I don't think -- I mean, he spent a lot of time on how wonderful -- I should say the witness -- on all the things FDA did tracking these things, which they didn't do; reviewing them which there's no evidence they did, and I was going to cover that with her. Of course, I don't have to if you strike it. Of course, I would have to ask you for more time. I have told them I'm not doing that for this trial. If someone else wants more time they will have to ask for it. 01:11PM

But let's go with a limiting instruction. I mean, let's go with the striking the evidence, Your Honor. And however you said it, you probably wrote it down. But if it's a powerful instruction for them to disregard all of that, we'll move forward. 01:11PM

THE COURT: Mr. North. 01:12PM

MR. NORTH: Your Honor, we would object to the instruction. I believe that it is too broad. It basically would be asking this jury to disregard 50 percent of her testimony about the communications with the FDA. If it was very specific to the Dear Doctor and Dear Colleague letter, that might be something else. But if it's going to be as broad as the Court styled it, we think we were entitled to get that information in. The evidence is there. And if the Court really believes the door was opened, I think the best solution is a limited subset of evidence as opposed to a broad 01:12PM 01:12PM

instruction that eliminates from the jury's consideration clearly relevant evidence under Georgia law.

THE COURT: All right. My conclusion is that if we were to go into the road -- down the road of introducing the death evidence it would present two problems: One would be I think it's a slippery slope and I think we'd have a hard time controlling it. The second is I think it puts plaintiff at an unfair advantage because the plaintiff has limited time left in the trial. They have allocated their time to issues that we were going to address which did not include the death evidence. 01:14PM
And I think with that limited time it puts them in a box if now we have to spend a half hour on each side talking about death evidence.

So my conclusion is that's not the right way to solve the problem. As a result, I'm going to give a limiting 01:15PM
instruction to the jury which will be as follows. I'm going to tell the jury to disregard the following categories of evidence: That Bard sent letters to doctors about complications with the Recovery Filter; that Bard told the FDA what it was seeing with the Recovery Filter on the basis of 01:15PM
information it gathered in the postmarket setting and told FDA of its plans to send the letter; FDA reviewed the letters, made suggestions, Bard accepted them and sent out the letter. I'm going to tell the jury to disregard that evidence.

I'm not going to explain why, because that would be 01:15PM

hazardous in my view and me commenting on the evidence. I have already told them I'm going to instruct them to disregard evidence. I'm going to do it.

I will tell them when they come back in we have taken 17 minutes of their time in an effort to save time in the trial which is the overall objective so they know we have been trying to do that. And that is the way in which I'm going to solve this problem. 01:16PM

Okay.

MR. NORTH: Just so the record is clear, can I just offer an objection to one portion of that limiting instruction? 01:16PM

THE COURT: Yes.

MR. NORTH: And that's the part where you are going to tell them to disregard the fact that Bard was conveying complaint information to the FDA. I think that's broader than just the Dear Doctor or Dear Colleague letter. 01:16PM

THE COURT: It's going to be specific to Recovery Filter complications in connection with the Dear Doctor letter.

MR. NORTH: If it's limited to the Dear Doctor letter then my objection is moot. 01:16PM

THE COURT: All right. Let's bring them in.

(Jury in at 1:17 p.m.)

THE COURT: Thanks for your patience, Ladies and Gentlemen. We have been in here for the last 20-plus minutes resolving an issue that I think will shorten the trial. Well, 01:18PM

I don't want to suggest we're going to end before we told you but it's not going to run over. We're trying to keep our arms around this time limit so we can get the trial done in the amount of time we discussed.

What I want to do now is give you a limiting instruction. You remember that I told you at the beginning of the trial I may instruct you to disregard some evidence. I'm going to do that now. 01:18PM

So this is the evidence that you have heard this morning that I am going to instruct you to disregard. It's the following categories: Bard sent letters to doctors about complications with respect to the Recovery Filter. In connection with those Dear Doctor letters, as they have been referred to, Bard told the FDA what complications it was seeing with the Recovery Filter in the postmarket setting. The FDA reviewed proposed letters, made suggestions which were accepted and the letters were then sent out. 01:18PM

My instruction to you is to disregard that evidence when you are deciding the case.

All right. Let's continue with the cross-examination. 01:19PM

MR. LOPEZ: Thank you, Your Honor.

CROSS-EXAMINATION (Resumed)

BY MR. LOPEZ:

Q. Dr. Tillman, hope you had a good lunch.

A. I did. Thank you. 01:19PM

Q. I know we talked about this a little bit, but I just want to make it clear that the documents that you were provided by Bard or had access to, you didn't go through the documents to look for maybe some test results or some information that was different than what Bard provided to FDA so that you could render an opinion as to whether or not Bard actually provided FDA with everything FDA should have had for any of the 510(k) applications. Is that true? 01:20PM

A. So I would say it's true that I did not deliberately look at the information I had and make sure everything I thought FDA should have was provided to FDA. I did not actively engage in that activity. 01:20PM

Q. So in your words, you were not acting as an auditor or an investigator where you were going through Bard's records to determine if there was something that should have been submitted to FDA that wasn't, in other words, that wasn't your role or responsibility for purposes of being an expert in this case. True? 01:20PM

A. That is true.

Q. And did you go look at any of the bench testing or any of the animal testing that Bard had done with respect to any of these filters to determine whether or not there were some test results that show that there were product performance failures that Bard kept to themselves and didn't send to FDA and should have sent to FDA? 01:20PM 01:21PM

A. So I certainly looked at bench tests. Some of the reports were submitted to FDA. Some of then weren't. It was not my intent, once again, to audit those or to determine what should or should not have been sent to FDA.

Q. Were you actually provided with some testing, bench testing, where any of their filters had failed performance specifications that they kept from FDA and didn't send to FDA? 01:21PM

A. So in my opinion, I did not see any valid scientific evidence that suggested that a Bard filter was not performing according to specifications. 01:21PM

Q. Okay.

A. I did see -- sorry -- some individual test deviations or test items that suggested that the performance was -- that some of the data, the information Bard was seeing was not entirely consistent with the specifications, but I think some of that might have been due to problems with the test setup or other testing limitations. 01:22PM

Q. Now, when a device like these filters we have been talking about here are going through a 510(k) process the FDA doesn't actually even get the device, right? They just get a schematic of the device? 01:22PM

A. So FDA can request a sample of the device if it wants. It doesn't do that very often. And it is my understanding that FDA did not actually have a sample of this device. So that is correct. 01:22PM

Q. They didn't get to hold like the Simon Nitinol Filter in one hand and the Recovery Filter in the other to inspect it, or any other filters? They couldn't -- they didn't do any physical inspections of the device, right?
A. I think that that's probably true, yes. 01:23PM
Q. Of course, they don't test devices themselves. True?
A. FDA only rarely does device testing and they did not do any testing in this case.
Q. And they didn't tell Bard what tests to run. Bard chose their own tests to run with respect to these 510(k) 01:23PM applications. Is that true?
A. Well, there is special control guidance documents.
Q. I understand. My question is a little different. I don't mean to interrupt. I'm talking about choice right now, not whether or not there was a guidance document. 01:23PM
Did FDA choose what tests they were going to run for these 510(k) applications or did Bard choose the tests they were going to run?
A. So Bard certainly chose the tests it would run.
Q. Thank you. And then the FDA would rely on whatever results 01:23PM happened from these tests to be accurately and honestly summarized for FDA. True?
A. So in the special 510(k)s, Bard provided a summary of the tests. In the traditional 510(k)s Bard provided the actual test reports and FDA would have actually reviewed the test 01:24PM

reports themselves.
Q. Now, you mentioned that you thought the Recovery was an appropriate predicate for the G2. Do you remember saying that?
A. Yes, I do.
Q. And you know the G2 first cleared as a permanent-only device, right? 01:24PM
A. That is correct.
Q. And you knew that the Simon Nitinol Filter was a permanent-only device, true?
A. Yes. 01:24PM
Q. And did you see in the material that you reviewed that the safety profile between the Recovery Filter and the Simon Nitinol Filter revealed that the Recovery Filter was dramatically more dangerous and had dramatically more complications than the Simon Nitinol Filter? 01:25PM
A. So I don't agree with your characterization of the performance of the Recovery Filter.
Q. So if the Simon Nitinol Filter had three fractures in Bard's files in 15 years and the Recovery Filter had 75 or 80 fractures, you think that was comparable performance? 01:25PM
A. I don't think you can compare those numbers without understanding what the denominator is in terms of how many devices are out there.
Q. Was there any evidence that you saw where Bard told doctors or patients that receive either the G2, the G2X, or the Eclipse 01:25PM

Filter, or were candidates for either, that those filters were under retesting and redesigning at the time that they were using those devices?
A. So I don't -- I did not see any evidence or any information to suggest that Bard told physicians that it was in the process of making modified versions of those devices. 01:26PM
Q. Now, you would agree with me that if you have a design deficiency or a design defect that you have recognized that is probably contributing to an increased complication, increased risk of your device, you don't fix that by just warning about known complications. Don't you agree with that? 01:26PM
A. So I think if there is a design defect with a device then ideally, you would like to try to redesign the device to correct it. If you can't redesign to correct it and you can't protect the user, then the appropriate thing is to warn against it. 01:26PM
Q. But you should always look to redesign first, and if you can't redesign then you put out a warning?
A. If it's possible to redesign the device to correct the problem without making something else worse, then yes, that would ideally be -- 01:27PM
Q. And if the data that Bard has is that increased risks that we identified in our device is because of a design, some design issues, the warning would be, we have an increased risk of complications with our device because we have identified some 01:27PM

design deficiencies. Wouldn't you agree that's the most appropriate warning?
A. So sounds like there's a hypothetical here, which is that if a company has identified design defects then should it warn people that those defects occur? If that's the hypothetical then yes, I would say that that would be appropriate. 01:27PM
Q. Okay.
MR. LOPEZ: Can I have trial Exhibit 696, please?
BY MR. LOPEZ:
Q. Do you see that, Dr. Tillman? You recognize this document, correct? 01:28PM
A. Yes, I do.
Q. And this is a document -- tell the jury who is or what is GAO?
A. So GAO is the General Accountability Office which is a -- or I guess Government Accountability Office which is a part of the U.S. government that is tasked with going out and doing studies and investigations of parts of the government. So if Congress wants to know more about what FDA is doing, they can go to the GAO and say, we'd like you to do a report on FDA. Here's the questions we want you to look into. And then GAO goes off, they do a study, and write a report. So this is a GAO report. 01:28PM
Q. And you are familiar that the GAO has done a number of reports regarding the FDA's -- some of the shortcomings of 01:28PM

FDA -- some of the resource issues that they have? You understand that, right?
A. Oh, yes. I'm very familiar with GAO has done many reports about FDA.
Q. And this is a copy of a report that you are very familiar with, right? 01:29PM
A. Yes, I was certainly familiar with this report at the time I was at the FDA.
MR. LOPEZ: Your Honor, I would like to offer 696 into evidence at this time. 01:29PM
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted.
MR. LOPEZ: And could I show it to the jury, Your Honor?
THE COURT: You may. 01:29PM
BY MR. LOPEZ:
Q. And this is a document dated June 18, 2009, and it's shortcomings in FDA's premarket review, postmarket surveillance, and inspections of device manufacturing establishments. Correct? 01:29PM
A. Yes. That is what this report was about.
Q. What was your position at the FDA at this time?
A. So at this time, I was the Director of the Office of Device Evaluation.
Q. And you had an opportunity, when they were preparing this 01:29PM

report, to actually review it and make any suggestions or corrections about its content. True?
A. So when GAO finishes writing a report they give a draft to the organization and give you the opportunity to correct any errors of fact. You are not allowed to correct their conclusions, but if they've got numbers that are wrong or other errors of fact then you are supposed to point those out. And I did do that with this report.
Q. I don't have the time, nor would I want to if I did. But I am going to point out a couple things in this report. 01:30PM
MR. LOPEZ: Could you go to the next page, Gay?
And could you highlight the second full paragraph where it says "FDA also faces challenges." Blow it up for Dr. Tillman.
BY MR. LOPEZ: 01:30PM
Q. Dr. Tillman, that reads: The FDA also faces challenges in postmarket surveillance of medical devices. In 2008 GAO reported that the number of adverse event reports associated with medical devices increased substantially from 2000 to 2006.
Do you see that? 01:31PM
A. Yes. I see that.
Q. Do you see both GAO and FDA have identified shortcomings in FDA's postmarket oversight. Did I read that correctly?
A. Yes, you did.
Q. For example, in 2006 FDA reported that the agency's ability 01:31PM

to understand the risk related to the use of medical devices is limited by the fact that the volume of submitted reports exceeded FDA's ability to consistently enter or review the reports in a routine manner.

Did I read that correctly? 01:31PM

A. That is what GAO found at the time this report was written, yes.

MR. LOPEZ: Can we go down to the bottom of that page, Gay, please. Just the last sentence there at the very bottom.

BY MR. LOPEZ: 01:31PM

Q. Taken together these shortcomings in both premarket -- and premarket would be 510(k) applications, right?

A. So this report was not about the broad premarket program. It was about a very narrow issue with the premarket program, but just to be clear about that. 01:32PM

Q. Taken together these shortcomings of both premarket and postmarket activities raise serious concerns about FDA's regulation of medical devices. Correct?

A. That is GAO's conclusion, yes.

MR. LOPEZ: Next, the next page, Gay, in the middle there. Middle paragraph. 01:32PM

BY MR. LOPEZ:

Q. FDA reviews submissions for thousands of new devices filed each year to decide whether they should be allowed to be marketed in the United States and is also responsible for 01:32PM

oversight of thousands of devices already on the market.

Correct? Did I read that right?

A. That is what it says.

MR. LOPEZ: And then the next paragraph down, Gay, please. 01:33PM

BY MR. LOPEZ:

Q. Recently concerns have been expressed about FDA's ongoing ability to fulfill its mission of ensuring the safety and efficacy of medical products including drugs, biologics, and devices. 01:33PM

Do you see that?

A. I see that.

Q. And then the demands of the agency have soared in recent years. This investigation revealed that. Is that what it says? 01:33PM

A. That's what it says, yes.

MR. LOPEZ: And then let's go to Page 14, Gay. It would be probably Page 17 of the actual exhibit, Page 14 of the document. Two more pages. The middle paragraph.

BY MR. LOPEZ: 01:33PM

Q. We and FDA have identified shortcomings in FDA's post-market surveillances. In 2006 FDA reported that the agency's Center of Devices and Radiological Health's ability to understand the risks of adverse events related to the use of medical devices, whether used in the home of a patient, in a 01:34PM

hospital, in a laboratory, or in the office of a private practitioner is limited both by lack of informative validated adverse event reports and by lack of quality epidemiologic information.

Did I read that right? 01:34PM

A. Yes. That's what GAO found in 2006.

Q. Well, there's been other reports since then, right? I mean, there have been reports in 2008, 2009 that have similar findings. Are you familiar with that?

A. I don't think the findings are completely the same but I would agree that GAO has continued to express concern about FDA's ability to perform its mission in the time frame that you are talking about. 01:35PM

Q. And you have seen a number of these reports where the FDA, I mean, they are good people, they are scientists, but they're just overwhelmed sometimes and they just can't do the job that we might expect them to do, right? 01:35PM

A. At the time that this report was written, that's true. Since then their resources have increased significantly.

MR. LOPEZ: Okay. Those are the only questions I have at this time, Your Honor. 01:35PM

THE COURT: Redirect?

MR. NORTH: No further questions, Your Honor.

THE COURT: Thanks, Dr. Tillman. You can step down.

MR. NORTH: Your Honor, at this time Mr. Rogers is 01:36PM

going to present Dr. Clement Grassi.

MR. ROGERS: Your Honor, I understand he's in the restroom.

THE COURT: Okay. If you want to stand up, Ladies and Gentlemen, feel free. 01:36PM

MR. ROGERS: Your Honor, in the interim can I hand up his report and some prior testimony of the doctor?

THE COURT: Yep. We'll trade you.

THE COURTROOM DEPUTY: Please come forward and raise your right hand. 01:38PM

(The witness was sworn.)

THE COURTROOM DEPUTY: Sir, if you could please state your name and spell it for the record.

THE WITNESS: Yes. Clement Grassi. C-L-E-M-E-N-T, G-R-A-S-S-I. 01:38PM

THE COURTROOM DEPUTY: Thank you, sir. Please come have a seat.

CLEMENT GRASSI, M.D.

called as a witness herein, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ROGERS:

Q. Good afternoon, Dr. Grassi.

A. Good afternoon.

Q. Can you introduce yourself to the jury, please? 01:38PM

A. Yes. My name is Clement Grassi, and I'm a practicing diagnostic and interventional radiologist.
Q. Doctor, what is going to be the focus of your testimony today?
A. The focus will be for me to speak about and render opinions on the SIR guidelines and the topic of IVC filters. 01:39PM
Q. And when you use the abbreviation SIR, what are you referring to?
A. That refers to the Society of Interventional Radiology.
Q. And would it be okay with you if we called it SIR for short during the course of your testimony? 01:39PM
A. Yes.
Q. Doctor, let me ask you some questions about your background and your education and training.
Can you tell the jury where you went to college, please? 01:39PM
A. Yes. I attended Harvard College.
Q. When did you finish Harvard?
A. That was in -- I graduated in 1976.
Q. And did you go to medical school thereafter? 01:39PM
A. Yes, at Tufts University School of Medicine.
Q. Is that also in Boston?
A. It is.
Q. And after medical school, did you do a what is something called an internship? 01:39PM

A. Correct. In my internship or first post-graduate year one I was at the Massachusetts General Hospital in Boston.
Q. And what types of things would you have done during that internship that year?
A. The internship is required for certification licensing. It includes clinical experience, seeing and treating patients. 01:40PM
Q. And is the Massachusetts General Hospital one of the hospitals that is also affiliated with Harvard?
A. Yes, it is. It is one of the Harvard Medical School teaching hospitals. 01:40PM
Q. Doctor, after that, did you complete a residency in radiology?
A. Yes. I was in a residency at the Beth Israel Deaconess Hospital also in Boston.
Q. What year did you complete your residency? 01:40PM
A. That was in 1985.
Q. And Doctor, can you tell us was your residency in diagnostic radiology?
A. Correct. Radiology training during the residency program for general radiology is in the field of diagnostic radiology. 01:41PM And then graduates may or may not continue with additional subspecialty training.
Q. And can you tell us briefly what you mean by diagnostic radiology?
A. Diagnostic radiology is the practice of imaging 01:41PM

interpretation and integration in terms of reporting for patient care.

Q. So Doctor, if we think of a doctor in the hospital typically holding up an X-ray and looking at it and trying to discern what's in there, is that diagnostic radiology? 01:41PM

A. Yes, overall.

Q. And so after that, did you do a fellowship?

A. I did. I did a two-year fellowship in interventional and cardiovascular radiology.

Q. Where was that? 01:42PM

A. Brigham and Women's Hospital in Boston.

Q. Is that also affiliated with Harvard?

A. It is. It is the third major Harvard teaching hospital.

Q. And very briefly, can you tell the jury the difference between diagnostic radiology and interventional radiology? 01:42PM

A. Well, diagnostic radiology involves, as I mentioned, the interpretation of images and the application of those findings to patient care. Interventional radiology is a subspecialty in which practitioners will use various catheter-based and other image-guided technique to perform procedures, again, for the 01:42PM benefit of patients.

Q. And Doctor, after your fellowship in interventional radiology did you do some teaching?

A. I did. I was asked to continue as a staff member at Brigham and Women's Hospital. And the responsibilities there 01:42PM

in addition to the clinical practice and research included teaching.
Q. Who were you teaching?
A. I was teaching fellows, residents, and also medical students including Harvard medical students. 01:43PM
Q. So when you say you were teaching fellows, does that mean were you teaching doctors who were in the process of learning to be an interventional radiologist about how to do that?
A. Yes. That's right.
Q. Doctor, tell us where you currently work, please. 01:43PM
A. I'm currently with Partners Healthcare, and I also work for Hallmark Health. And those hospitals are in the greater Boston area just north of Boston.
Q. How long have you been in Boston?
A. I have really been -- grown up in Pennsylvania, but more of 01:43PM my life has been in New England or just outside Boston.
Q. Doctor, are you licensed to practice medicine?
A. Yes, in the state of Massachusetts.
Q. Are you board certified?
A. Yes, I am. 01:44PM
Q. And so Doctor, how long have you been in the practice of medicine currently?
A. I have been practicing now for 38 years.
Q. And have you been the director of vascular and interventional radiology at certain hospitals? 01:44PM

A. Yes. After I had left Brigham and Women's Hospital I had taken additional positions, promotion positions. One of those was as director at the Boston VA Health Services in the Boston area, and I directed interventional radiology.

Q. Do you implant inferior vena cava filters? 01:44PM

A. Yes, I do.

Q. And do you retrieve inferior vena cava filters?

A. Yes. I also retrieve them.

Q. How long have you been doing that?

A. Well, implantation, as you know, because of permanent devices, would have been performed really since the time of my fellowship. And more recently, over my several years of practice, it would also include retrievals which has been more recently. 01:44PM

Q. And have you had an interest in inferior vena cava filters throughout the course of your career? 01:45PM

A. It really has been an interest of mine. It's been one of my career interests in terms of venous thromboembolic disease, prevention of pulmonary embolism, and the use of mechanical protection by vena cava filters. 01:45PM

Q. Have you published articles in the peer-reviewed medical literature or inferior vena cava filters?

A. Yes. I have several published articles.

Q. Have you served as an investigator for clinical trials that were studying inferior vena cava filters? 01:45PM

A. I have. I have participated as a co-participant, and I have also been the principal investigator for one of the IVC filter trials while I was a staff member at Brigham and Women's Hospital.

Q. So Doctor, how long, approximately, would you say that -- well, let me strike that question. 01:46PM

Doctor, when is the last time that you would have implanted an inferior vena cava filter?

A. I would say about two and-a-half weeks ago.

Q. When is the last time you would have retrieved one? 01:46PM

A. Approximately three weeks ago.

Q. And Doctor, let me ask you some more questions about the Society of Interventional Radiologists or the SIR.

Can you describe for the jury just generally what that organization is? 01:46PM

A. Yes. The Society of Interventional Radiology promotes and promulgates information both for educational purposes and for the dissemination of techniques related to interventional radiology. Although it's based in the United States, it's really an international organization. 01:47PM

Q. About how many members are there of that organization?

A. As of this date, I would say it probably exceeds the high 5,000s.

Q. Doctor, is there something you can become in the SIR called a fellow or a senior fellow? 01:47PM

A. Yes, there is. That's an additional position in addition to standard membership. And it's not to be confused with the term of fellow that we just talked about for training purposes. It's really an honorary position that's granted to those who apply who are members of the SIR, and who then have either published in the field, created or promoted new advances, or otherwise distinguished themselves in the field of interventional radiology. 01:47PM

Q. Do you also have to receive letters of support from other members of the SIR who are fellows? 01:48PM

A. That's correct. There's an application process.

Q. And Doctor, are you a senior fellow in the SIR?

A. Yes, I am.

Q. How long have you been a senior fellow?

A. Since approximately 1993. 01:48PM

Q. Let me ask you about some of your other work within the SIR. Have you been involved in certain committees of the SIR?

A. I have. Because of my interests I have been very active in several of the committees there.

Q. And can you tell us, have you chaired any of those committees? 01:48PM

A. I have; specifically two of them. I was a member of the Technology Assessment Committee which looks at new and interesting technologies in the field, and I became a chair there for three years. And I have also been a member of the 01:48PM

Standards of Practice Committee. And after working in that committee I was a chair of the SIR Standards of Practice Committee also for three years.

Q. And what does that committee do, the Standards of Practice Committee? 01:49PM

A. That committee is created by the SIR in an effort to educate, summarize information for practitioners and for those working in the field, and to create documents, both electronic and in print, that will guide practitioners in the field.

Q. And were you involved in the preparation of some guidelines as part of that committee that relate to the use of inferior vena cava filters? 01:49PM

A. Yes. I was actually a first author of one such publication.

Q. When were those guidelines published? 01:49PM

A. They were published in 2001.

Q. And did they go through a peer-review process?

A. Yes, they did, a very strict one.

Q. And were the guidelines, once they were published, were they provided to all members of the SIR? 01:50PM

A. They were. They were available after publication on line and also in a print version. They were published in the official journal of the Society of Interventional Radiology which is the JVIR, or Journal of Vascular Interventional Radiology. 01:50PM

Q. So Doctor, is it fair to say that the guidelines you worked on and that were published were widely disseminated within the medical community?
A. They were. And in answer to your question, there was a period where they were available also prior to their final publication in which members of the Society and those working in the field in general could submit comments in regard to the publication of the document itself. 01:50PM
Q. Okay. Thank you, Doctor. I'm going to ask you a little bit more about that in a minute. 01:51PM
MR. ROGER: But can we pull up Exhibit 7132, please.
BY MR. ROGERS:
Q. Doctor, do you see on your screen there Exhibit 7312?
A. Doesn't seem to be coming up quite yet. Now it is.
Q. And is this a copy of the published version of the guidelines that you were describing? 01:51PM
A. Yes, it is.
Q. And what is the title of these guidelines?
A. The title is: Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. 01:51PM
MR. ROGERS: At this time, I would move for admission of 7132.
MR. CLARK: Your Honor, we would object as hearsay.
MR. ROGERS: Your Honor, under Rule 801(c) we don't 01:52PM

believe this document is hearsay because it is not being offered for the truth of the matter asserted but is being offered instead for the information that was available within the medical community and to Bard in the 2001 time frame.

THE COURT: Mr. Clark. 01:52PM

MR. CLARK: Your Honor, we would disagree with that characterization. It's offering studies and information that is, in fact, offered for the truth of the matter asserted. We would not object to information from it being published under 803.18 as an authoritative text. I think Mr. Rogers has 01:52PM touched those bases, but we do not think it gets around the other problems.

THE COURT: I want to ask you a couple questions so let's talk briefly at sidebar.

You can stand up, Ladies and Gentlemen. 01:52PM

(Discussion was had at sidebar out of the hearing of the jury:)

THE COURT: Mr. Clark, in the Booker trial this was admitted with a limiting instruction that it was not to be considered for the truth of the matter asserted, only for 01:53PM notice and knowledge within the industry. My question to you is: If I were to admit it with that limiting instruction in this case, do you think that it is improper under the Rules of Evidence in some way?

MR. CLARK: I do in this particular circumstance. I 01:53PM

do not think there's been foundation laid. Yes, he said it went out to doctors but as far as the information, how they reacted, we talked about this a little bit with the Nicholson article. And I think that was the basis of your ruling to allow that was that it produced a specific reaction with Bard. We don't have any foundation that it has done that in the medical community in this particular case. 01:53PM

THE COURT: If that foundation is laid, do you think that admitting it with that limiting instruction would be appropriate? 01:53PM

MR. CLARK: Your Honor, I don't, because I think we're getting into what information the doctors are taking from this which gets into truths. I don't think that cures the problem so I would maintain my objection. I understand the Court's prior ruling. 01:54PM

THE COURT: I do think it needs that additional foundation. If it's going to be admitted for purposes of notice and knowledge there needs to be foundation that that's, in fact, the effect it had.

So I am not going to admit it at this point, but if you want to lay that additional foundation I will consider it at that point. 01:54PM

MR. ROGERS: Okay. We'll do, Your Honor.

(In open court.)

THE COURT: Thank you, Ladies and Gentlemen. 01:54PM

BY MR. ROGERS:
Q. Dr. Grassi, are you ready?
A. Yes.
Q. Let me ask you a few more questions about this document.
You told us earlier that it was published in 2001 and distributed to the all the members of the SIR. Is that right? 01:54PM
A. That's right. Because of the fact that the Journal of Vascular and Interventional Radiology is the official journal and is a benefit of membership, all of the members would have had access to this. 01:55PM
Q. So would it have gone to all 5,000 plus members of the SIR?
A. Correct, as well as being available electronically on the website.
Q. And Doctor, what is your understanding of how members of the medical community, including members of SIR, would have used this document? 01:55PM
A. They would have used it, and its intended purpose was as a summary document. The goal was to provide, in a summary fashion, comments which would help practitioners in their day-to-day work and all those working with vena cava filters. 01:55PM
Since in the literature there were literally hundreds of articles which had been published, but to my knowledge as of that time there was no real summary document, it was the opinion of the SIR executive committee that that was something that was greatly needed. 01:56PM

Q. And did the document that you put together summarize information about adverse events that were seen with IVC filters in individual doctors' practices?
A. Yes, it did.
Q. And was that information disseminated to the members of the SIR? 01:56PM
A. Yes.
Q. And so with that kind of information about the adverse consequences that a doctor may see about -- with an inferior vena cava filter, how were the doctors in the medical community supposed to use that information? 01:56PM
A. They would use it in a constructive fashion to look at the data presented, examine the thresholds or rates which we had quoted, and as described in the document, if in their practice they found that some of the complications or adverse events or other parameters met or exceeded what was quoted, then that should prompt for them a quality assurance review in their own department for their own personal use. 01:56PM
Q. Were these guidelines also available to other stakeholders in the IVC filter world such as IVC filter manufacturers? 01:57PM
A. Yes, they were.
Q. And was the data that was contained in your guidelines available for use by IVC manufacturers like C.R. Bard?
A. Because this was available on the website and published, it was available to them and to the public as a whole. 01:57PM

MR. ROGERS: Your Honor, I, again, move Exhibit 7312 into evidence.

MR. CLARK: Same objection, Your Honor.

THE COURT: All right. Ladies and Gentlemen, I'm going to admit Exhibit 7312 but with a limiting instruction that you have heard before, which is this document is not being admitted to prove the truth of what is asserted in the document. It is instead being admitted to demonstrate knowledge within this medical community and what was known by the community on the basis of these guidelines. 01:57PM 01:58PM

And with that instruction, the document is admitted.

MR. ROGERS: May we publish the document, Your Honor?

THE COURT: Yes.

BY MR. ROGERS:

Q. Dr. Grassi, let me first turn your attention, you have given us the title of the article previously. I do want to point out your name appears with several other names under the title. Can you tell us what that means, please? 01:58PM

A. Yes. So that I was the first author and as the first author responsible for the leadership on the document, and the additional dozen or so names here were my co-authors on the document. 01:58PM

The committee itself consisted of over 30 people, and these were the individuals who had participated directly in the publication and the review of the document. 01:59PM

Q. And so since -- with all these doctors whose names are listed, are they all interventional radiologies like yourself?
A. They are, and it includes a number of physicians who I must say are very talented and prominent in the field and many of whom you see here are still active within the SIR. 01:59PM
Q. And as the lead author, what were your responsibilities?
A. I was --
Q. Compared to the other authors?
A. Yes. I was responsible for being the leader on the document, being the prime author, delegating sections for 01:59PM review, creating subcommittee or working groups in terms of the construction of the document. And then I was the organizer and coordinator for our personal meetings and also for our conference calls.
Q. And before these guidelines were developed, were there any 02:00PM practice guidelines for interventional radiologists such as yourself about IVC filters?
A. Certainly as I mentioned there were a variety of publications on the subject, but to my knowledge before this there were no specific practice guidelines in a summary fashion 02:00PM that existed.
Q. And Doctor, before we get into the substance of some of the guidelines, let me ask you just a few questions about how this was put together.
Can you describe for the jury generally what the 02:00PM

process was that you went through in order to kind of bring these guidelines together?

A. It was a multi-step process, because as you can imagine, we felt obliged to be very comprehensive with the information we had. It started with a review of the literature by the SIR staff and ourselves in collecting all of the known articles by sources like PubMed, MEDLINE, and Google search. Then of those hundreds of articles the committee looked at them and we boiled those down to the ones which we felt were the most pertinent. 02:00PM 02:01PM

From the information in those articles there was text and writing which went on, and that process was extensively reviewed over about a two-year period. As I mentioned, we conducted personal committee meetings at two different annual meetings; one the annual meeting of the SIR, which usually occurs in the Spring, and also the meeting of the Radiological Society of North America which regularly occurs at the end of November to the beginning of December in Chicago. 02:01PM

Q. Once there was a draft of these guidelines ready, what was the process thereafter? 02:01PM

A. After the draft, it was important that the working members of the committee review it and that there be a give and take about the facts within it. So we conducted conference calls, usually in the evenings, anywhere between Monday and Friday. They might be quite lengthy, lasting for two or three hours. 02:02PM

We would go through actually each section of the document, part by part, reviewing the text, the tables, references, and listening really to everyone's opinion on the subject; what they felt was important to exclude and what would not be included. 02:02PM

Q. And did a draft of the document go to the executive committee for the SIR?

A. It did. After this preliminary process then that was submitted to the executive committee and then there was further action. 02:02PM

Q. And at one point, did the draft document get posted on the SIR website so all interventional radiologists who were members of that organization could comment on the guidelines?

A. It did. It was available for commentary, and after a period of commentary, those notes and e-mails were collected. 02:03PM And then that was synthesized in the document and then the document was, once again, submitted now to the Journal of Vascular Interventional Radiology to the editor-in-chief for their review.

Q. So once it was submitted to the editor, did it go through 02:03PM an additional peer-review process?

A. Yes, by the editor and the co-editors.

Q. And then thereafter was it published?

A. That's correct.

Q. And Doctor, again, I believe you said it was published in 02:03PM

2001, is that right?
A. Yes.
MR. ROGERS: And Scott, if you would, can we pull up Table 2 which is on Page 7312, excuse me, third page.
BY MR. ROGERS: 02:03PM
Q. Doctor, do you see on your screen there Table 2?
A. Yes.
Q. Is this something that was a part of the guidelines that you put together?
A. Yes, it is. 02:03PM
Q. And underneath Table 2 it says "other trackable events." Do you see that?
A. Yes.
Q. And can you describe for the jury what that means? What are other trackable events? 02:04PM
A. Well, it's important to understand that these are medical parameters that in my opinion and in the opinion of the committee members were important for physicians and those working with interventional devices, IVC filters. They include IVC penetration, migration, filter fracture, axis site 02:04PM thrombosis, insertion problems, and a category of other.
Now, it's important to understand that these may not be adverse events. In many cases these were patients who had no ill effects whatsoever. But we felt that for the purpose of medical completeness the practitioners should be aware of these 02:04PM

events and know about them.
Q. And Doctor, what are these numbers that come after those categories? For instance, after IVC penetration, we see 7, 17, 19. Can you tell us what those are?
A. Those were the numbered references or citations to the articles that are included under the reference list that we referred to for these categories. 02:05PM
MR. ROGERS: Scott, would you go to the last two pages, please, and let's show the reference list.
BY MR. ROGERS: 02:05PM
Q. And Doctor, it looks like the reference lists run through the Number 54. Is that right?
A. Yes.
Q. And so does that mean -- well, tell us what that means. Are these the 54 medical articles that were cited in your guidelines? 02:05PM
A. They are. And this does not mean that these are the only articles that dealt with the subject. But of the hundreds that I had mentioned in our review of the literature, these were the ones which the committee felt were the most significant ones. 02:05PM
Q. And do all of these articles that are cited in the guidelines, do they all deal with permanent IVC filters?
A. They do, because on a time frame it's important to understand that this was written at the time that vena cava filters were available as permanent devices. The retrievable 02:06PM

or option-type filters came later.
Q. And at the time you did this search of the worldwide literature, roughly how many articles are out there? Do you have any idea, about IVC filters?
A. I would say it would be in the hundreds, perhaps over a thousand. 02:06PM
Q. And did you cull down the articles that you wanted to cite down to these 54?
A. Yes.
MR. ROGERS: Scott, let's go back to Table 2 please. 02:06PM
BY MR. ROGERS:
Q. And Doctor, we pulled out Table 2, and on the right-hand side there's something called reporting rates. Can you explain to the jury what that is?
A. So the reported rates are a range which we provided in the table for the benefit of practitioners. And they give the range over which we observed these particular parameters occurring. For example, IVC penetration on the first line, in those articles was cited as occurring with a frequency of anywhere from zero to 41 percent. 02:07PM
Q. And how did you come up with that range?
A. It was by looking through the articles, reading them, and seeing what the investigators reported.
Q. So if there's zero, does that mean that there was an article out there that found zero IVC penetrations in the study 02:07PM

that they did?
A. That's right, whereas one of the other articles may have reported IVC penetration in as high as 41 percent.
Q. Okay, Doctor, I want to talk a look at the line that says filter fracture. Do you see that, in the third one down? 02:08PM
A. Yes.
Q. So what is the reported rate for IVC filter fracture?
A. The reported rate is between 2 and 10 percent.
Q. And Doctor, let's take a look at one of the citations that you relied on. Do you see number 17 there? 02:08PM
A. Yes.
MR. ROGERS: And Scott, if you would, can you pull up 7002, please?
BY MR. ROGERS:
Q. Doctor, do you have that on your screen? 02:08PM
A. Yes, I do.
Q. And what is the title of that article?
A. This article is Percutaneous Inferior Vena Cava Filters Follow-Up of Seven Designs in 320 Patients.
Q. Where was this article published? 02:08PM
A. This is published in the so-called Grey Journal of Radiology. That is the official journal of the Radiological Society of North America, or we refer to it as the RSNA.
Q. Is that a peer-reviewed medical journal?
A. It definitely is. 02:09PM

Q. Would you consider this article to be a reliable article?
A. Yes. It's one of the preeminent journals.
MR. ROGERS: If you would, please, Scott, let's go to Page 3.
BY MR. ROGERS: 02:09PM
Q. Well, before we get there, Doctor, let me ask you a general question. In this particular article what were the authors studying? What were they looking at?
A. The authors were looking at IVC filters in general and commenting specifically on the complications which they saw 02:09PM associated from a variety of devices.
MR. ROGERS: And let's pull out Table 2, if you would, please.
BY MR. ROGERS:
Q. And Doctor, is this a table that appears in that article? 02:09PM
A. Yes, it does.
Q. And running across the top, we see that there are -- it says complications, and then there are several abbreviations. Are all those abbreviations the abbreviation for a particular filter? 02:10PM
A. That's correct.
Q. Are all these filters permanent filters?
A. Yes, they are.
Q. And, for instance, the first two, there's BN1 and BN2 what are those? 02:10PM

A. So that stands for bird's necessary or specifically the Gianturco-Roehm Bird's Nest Filter. The one refers to the first version or the first iteration, and the numeral 2 refers to the second.
Q. And what would the N be that's in the middle there? 02:10PM
A. The N in this article is the abbreviation for the so-called Simon Nitinol Filter with the N representing Nitinol.
Q. How about the one that says VT. What was that?
A. That would stand for the Vena Tech Filter.
Q. What about TG? 02:10PM
A. That would be the Titanium Greenfield Filter.
Q. And Doctor, let's take a look, I guess, first at the fracture rate that's reported in this article.
MR. ROGERS: Can you pull that line out, please, Scott? Can you go one more line down? Thank you. 02:11PM
BY MR. ROGERS:
Q. And so what are the rates here that are being reported for fracture that are seen in these filters?
A. Well, these are the reported rates according to the various filter types that we have talked about. 02:11PM
Q. So, for instance, with the Bird's Nest 1 and Bird's Nest 2, what was the fracture rate that was being reported according to this article?
A. So the Bird's Nest Type Number 1 showed 1 in 26 or a rate of 4 percent. The Bird's Nest Filter 2, one fracture in 32, or 02:11PM

a rate of 3 percent.
Q. What was the reported fracture rate for the Simon Nitinol Filter?
A. The Simon Nitinol filter under the line N 10 showed 2 of 17 or rate of 12 percent. 02:11PM
MR. ROGERS: Scott, can you pull out the line on migration, please.
BY MR. ROGERS:
Q. Doctor, do you recall how migration was defined in this article? 02:12PM
A. Yes. It's my understanding that migration that is representing a significant change of the filter position within the vena cava was defined as a change of two centimeters or greater.
Q. Let's take a look just to make sure we're accurate. 02:12PM
MR. ROGERS: Can you go to Page 2, please, Scott, and that top section? I think we're on Page 4. Let's go over to Page 2. And that middle paragraph or middle column, can you pull out the section on migration, please.
BY MR. ROGERS: 02:12PM
Q. So Doctor, from this portion of the article, what was the definition of migration? How is that defined?
A. Yes. So I just want to correct myself. In this particular article it was a movement, cranial or caudal, cranial meaning superior, or toward the head; caudal meaning inferior, or 02:13PM

toward the feet of actually more than one centimeter. Different articles one will find may actually use either the one-centimeter or the two-centimeter parameter.

Q. So any movement within the inferior vena cava up or down by more than one centimeter was considered migration? 02:13PM

A. Yes.

MR. ROGERS: Scott, can you go back to the table, please. Pull out the migration line.

BY MR. ROGERS:

Q. So Doctor for this particular line of migration for that Bird's Nest 1, what was the percentage of migration that was reported? 02:13PM

A. The percentage of migration on the left is 12 percent.

Q. And how about the rate for the Simon Nitinol Filter? What was the rate there? 02:13PM

A. The rate for the Simon Nitinol Filter is 12 percent.

Q. And for the Titanium Greenfield, what was the rate reported for migration?

A. Yes. In this case, three out of six, and with that smaller number the rate is actually 50 percent. 02:14PM

Q. Doctor, let's look also at the line called IVC penetration.

MR. ROGERS: Can you highlight that line, please, Scott?

BY MR. ROGERS:

Q. And so Doctor, again, what are the rates that are reported 02:14PM

here for IVC penetration?
A. Moving from left to right, for example, with the Bird's Nest Filter, Type 1, 5 percent; with the Bird's Nest 2, 6 percent. With the Nitinol Filter that you had mentioned earlier, or Simon Nitinol Filter, there was a rate of 33 percent. 02:14PM
Q. How about for the Titanium Greenfield?
A. And the Titanium Greenfield, a rate of penetration of 50 percent.
MR. ROGERS: Would you please take that down and let's go back to the prior exhibit, please. Can we publish that for the jury, please? 02:15PM
THE COURT: Yes.
MR. ROGERS: Scott, if you would, can you pull back, that table please. 02:15PM
BY MR. ROGERS:
Q. So Doctor, now that we've got a little bit of an idea how some of these rates were put together, can you tell us what the migration rate was that's published in your article?
A. The migration rate is a reported range of between 0 and 18 percent. 02:15PM
Q. So looking then at the first three lines where you have penetration, migration, and fracture, were those rates all well known within the medical community when this was published in 2001? 02:16PM

A. Yes, they were.
Q. And were these -- were the information that was published used by practitioners such as yourself and in teaching institutions for fellows who were training in interventional radiology? 02:16PM
A. Yes. It would have been rates which were available to people in teaching hospitals as well as hospitals as a whole.
Q. And since your guidelines were published, have the guidelines from the Society of Interventional Radiology been updated from time to time? 02:16PM
A. Yes, they have, which is a regular process by the SIR.
Q. And what is the most recent edition of those guidelines?
A. There is actually a 2017 updated version, which is available through a publication with the American College of Radiology. 02:17PM
MR. ROGERS: Scott, would you pull up Exhibit 6842, please.
BY MR. ROGERS:
Q. And Doctor, do you have on your screen the most recent version of the SIR guidelines? 02:17PM
A. Yes, I do.
Q. And were these the ones that were published in 2017?
A. Yes. And you can see the date about the third of the way down. Says they were revised in 2016, and it's my understanding they were actually published in calendar 2017. 02:17PM

Q. And were these guidelines also submitted to a peer review process similar to what you described earlier?
A. Yes, they were.
Q. And are these, again, available to all the members of the Society of Interventional Radiology? 02:17PM
A. They are. They would be available to members of the Society of Interventional Radiology; the members of American College of Radiology, a separate large society. And because they are published they are available as knowledge to the public as well. 02:18PM
Q. And Doctor, do you consider these guidelines to be a reliable authority?
A. Yes, I do.
Q. And do you use these guidelines in your practice?
A. Yes. They are widely used. 02:18PM
Q. And so do these particular guidelines, since they were published in 2017, did they contain data on both permanent and retrievable filters?
A. In this case, because in the time period of 2016 to 2017, retrievable or option filters were available, these included both permanent and retrievable types. 02:18PM
MR. ROGERS: Scott, can you go to Table 2, please, and pull that up for the doctor. That's on Page 13. Yeah. There you go.
BY MR. ROGERS: 02:18PM

Q. Doctor, is there a Table 2 in the 2017 version similar to the Table 2 that was put together for the set of guidelines that you authored in 2001?
A. Yes, there is, and it's what you are showing now.
Q. And are the categories of potential complications that are listed in Table 2 pretty much the same as the ones that you published in 2001? 02:19PM
A. Yes. They are very, very similar.
Q. And for the one section called migration of filter, has there been something added on to that? 02:19PM
A. There is. The listing now reads migration of filter slash filter components.
Q. And what does that mean, migration of filter components?
A. Well, in thinking about the medical term migration, migration is usually defined as a movement of the filter itself. The use of filter components connotes that rather than being the filter as a whole, it might include movement of one portion, that is, one piece of metal of the filter rather than the filter in total. 02:19PM
Q. And what is the reported rate that's listed in the 2017 guidelines? 02:20PM
A. The rate is between 0 and 25 percent.
Q. And Doctor, roughly how many citations have been given in the 2017 guidelines in support of that reported rate for filter migration? 02:20PM

A. These look to be approximately 33 references.
Q. And have you reviewed those references?
A. Yes. I have seen the titles of all these citations.
Q. And do any of those references report any clinical data that was done on the Eclipse Filter? 02:20PM
A. Let's see. No. These would not include the Eclipse Filter.
Q. And so if they don't include data on the Eclipse Filter, what does that mean? What can you take away from that?
MR. CLARK: Objection. Foundation. 02:21PM
THE COURT: Overruled.
THE WITNESS: Yes. Well, I can say looking at this subjectively that the rate of my filter migration or filter component migration is based on filter devices other than the Eclipse Filter showing a rate of 0 to 25 percent. 02:21PM
BY MR. ROGERS:
Q. Okay. And let's take a look at filter fracture. What is the reported rate for filter fracture in 2017?
A. In this article, the reported rate is between 0 and 50 percent. 02:21PM
Q. And again, roughly how many citations are there in support of that rate?
A. Again, approximately 33.
Q. And Doctor, have you had a chance to review those citations that support that rate? 02:22PM

A. I have seen the titles of these reference citations.
Q. And do any of the titles that you see, do any of those appear to concern the Eclipse Filter?
A. No. These would not include the Eclipse.
Q. And then for IVC penetration, what is the rate that's reported there? 02:22PM
A. For penetration the rate is between 0 and 100 percent.
Q. And roughly how many citations are there in support of the penetration rate?
A. Again, just over 30. 02:22PM
Q. And have you reviewed those articles?
A. Yes. I have had a chance to see these article titles.
Q. And do any of those articles appear to concern the Eclipse Filter?
A. No. These would not include the Eclipse Filter. 02:22PM
Q. And so Doctor, again, does it appear that the complications of penetration, migration, and filter fracture are well known within the medical community today?
A. Yes. Based on the guidelines that we have talked about, these guidelines and the literature that's available and 02:23PM published, these pieces of information are well known.
Q. Doctor, the jury has heard testimony that filter migration, penetration, tilt, and fracture are interrelated and that specifically, that migration, tilt, and penetration can cause a filter to fracture. In your opinion, is that theory supported 02:23PM

by the medical literature?
A. Well, I can say that from my work on the committee and interaction with the members and in my own personal experience, certainly I have seen, or seen with colleagues, a variety of different complications with all filter devices. But I have not seen and have not seen proof of any relationship that you have just mentioned. 02:23PM
Q. And in the current version, the 2017 version of the guidelines that are published by the SIR, is there anything in those guidelines that relate to an inter-relatedness between filter complications? 02:24PM
A. Well, certainly the guidelines deal with either one or more than one complication related to a particular filter, particular patient. But there's no mention of any interrelated sequence of events in them. 02:24PM
Q. And Doctor, in all of your review of the medical literature, have you ever seen the term "cascade of events" as applied to IVC filters?
MR. CLARK: Your Honor, I don't think this is in his report. 02:24PM
THE COURT: Where is that in the report, Mr. Rogers?
MR. ROGERS: Your Honor, on Page 10 of his report he discusses that there is no information about interrelatedness amongst the various complication modes with IVC filters.
THE COURT: Where is that, please? 02:25PM

MR. ROGERS: It's on Page 10 of his report.

THE COURT: Yeah. Where? It's a dense page.

MR. ROGERS: Sure. I'm sorry. If you look under the section at the very top, first full paragraph, "relationship of IVC adverse events." 02:25PM

THE COURT: Let me read that.

The objection is overruled.

BY MR. ROGERS:

Q. So Doctor, let me ask you again. In your review of the medical literature, over the course of the years that you have been an interventional radiologist, have you ever seen the term "cascade" as applied to the concept of there being some relationship between various filter modalities -- excuse me -- complication modalities with filters and particularly tilt and perforation and migration leading to fracture? 02:25PM 02:26PM

A. Well, I am aware of comments using either a term similar to cascade, or cascade. But in my own personal experience, and in the articles that I have had a chance to read, I have not encountered any proof of such a pathophysiology.

Q. Doctor, are you charging for your time today? 02:26PM

A. Yes.

Q. And what is your hourly rate?

A. My hourly rate is $350 per hour.

Q. And have you been retained by my law firm or C.R. Bard to be an expert witness in this litigation? 02:26PM

A. Yes, via the Nelson Mullins law firm.
Q. Do you charge $350 an hour for all of the activities that you engage in as an expert witness?
A. Yes, I do.
Q. And Doctor, have all the opinions that you have expressed today been to a reasonable degree of medical certainty? 02:26PM
A. Yes.
Q. Thank you, Doctor. I don't have any further questions.
THE COURT: All right. Cross-examination?
MR. CLARK: Yes, Your Honor. 02:27PM

CROSS-EXAMINATION

BY MR. CLARK:
Q. Good afternoon, Doctor.
A. Good afternoon.
Q. I want to make sure I heard that right. Did you have some connection with Harvard in your professional experience? 02:27PM
A. Yes. Through my work, through a number of hospitals I have been affiliated with Massachusetts General, Beth Israel Deaconess, and more recently, Brigham and Women's Hospital which, as you know, are Harvard medical school teaching hospitals. 02:27PM
Q. I think I get the opportunity to talk to the people Bard has hired from Harvard in this case, so it's your lucky day.
You were asked questions by Mr. Rogers about compensation by the Nelson Mullins firm in this case. How much 02:27PM

have you charged for your work in this matter?
A. The more recent billing for this specific matter, and you are asking me for a total?
Q. Yes.
A. Yes. So the more recent billing which included imaging review, record review, and, of course, testimony is approximately $6,000. 02:28PM
Q. $6,000. And you have been working with -- for Bard on a consulting basis since 2010, is that correct?
A. That's correct. 02:28PM
Q. And is it fair to say that over the last eight years that your total billing on all matters you have handled on a consulting basis with Bard would approach six figures?
A. No. I don't believe it would be that much. I would have to actually, myself, go back and look at the billing since 2010. 02:28PM
Q. Well, if you testified a couple months ago that your billing had been around $37,000, and that did not include all prior work, would that give you some perspective that it might actually be over the course of the last eight years somewhere around six figures? 02:29PM
A. Off the top of my head, I would say, counselor, that it would be less than that because one would have to understand that the work, unlike my medical practice, is not constant, is not every week or every month. And so I work intermittently in 02:29PM

terms of my time and energies.

THE COURT: Mr. Clark, we're going to take a break at this point.

Ladies and gentlemen, we'll resume at 2:45.

(Recess from 2:29 until 2:45 p.m.) 02:29PM

THE COURT: Ladies and Gentlemen, for your information, to make up for a little bit of lost time, we'll go until 4:30 today.

You may continue, Mr. Clark.

MR. CLARK: Thank you. 02:46PM

BY MR. CLARK:

Q. Doctor, let's get into the SIR guidelines. These guidelines were published in 2001, correct?

A. Correct.

Q. And they are a collection of data that had been culled from 02:46PM medical literature, is that right?

A. Yes.

Q. And at the time of 2001, I think you told us that retrievable or optional filters were not yet on the market. Is that fair? 02:47PM

A. That's fair. They were not in clinical use.

Q. So at the time in 2001, that study related only to information concerning permanent filters, right?

A. Yes. As stated in the guidelines, that document dealt with permanent IVC filters. 02:47PM

Q. Now, in terms of studies you talked a little bit about the types of studies that went into the SIR guidelines. You have authored an opinion in this case that there's a certain hierarchy of studies with the first kind of gold standard being double-blinded controlled prospective studies. Do you remember that? 02:47PM

A. Yes.

Q. And you agree that that's the best level and most reliable level of a study, correct?

A. That would be the ideal in terms of the level of information for its accuracy and unbiased nature, yes. 02:47PM

Q. And as we get down the list in terms of that, then, one of the things that becomes concerning is that different studies can have different biases, either underreporting, over-reporting, selection bias, things like that. Right? 02:48PM

A. That's fair.

Q. And in terms of the -- you would agree that there are no what we might call Level 1 studies, that double-blind controlled prospective studies relating to the use of IVC filters. Fair? 02:48PM

A. To the best of my knowledge there are no double-blinded prospective multi-center Level 1 type studies available on IVC filters. That's right.

Q. And that's true today just like it was back in 2001, to the best of your knowledge? 02:48PM

A. Yes. To the best of my knowledge, that is still correct.
Q. Now, one of the categories you listed in your report is a Level 5 category in terms of strongest to weakest was collection of data including from the FDA's MAUDE database. Do you remember giving that opinion? 02:49PM
A. Category 5 that you are mentioning would be reports that might be singular reports, case reports, or other data which certainly could be read and used but is not a Level 1 study.
Q. And what you have rated the FDA's MAUDE database was Number 5 in your report, correct? 02:49PM
A. Correct.
Q. And for scientific reasons, it's most useful and most reliable to compare studies that are of the same category in terms of the data that's in there, correct?
A. Certainly in answer to your question, trying to compare study to study, it's most useful to look at data from comparable level studies. 02:49PM
Q. Apples to apples, right?
A. More or less.
Q. Now, you talked about the Ferris article which is Exhibit 7002. 02:49PM
MR. CLARK: Could you pull that up please, Gay? If you could go to Page 3, Table 2.
BY MR. CLARK:
Q. Do you remember this document? Was this the document that 02:50PM

you said was very important?
A. Yes. You are showing the Table 1, I believe, from the Ferris, et al., radiology article.
Q. And this was the table that was used to describe the rate of failure for different types of conditions, including IVC penetration, migration, and fractures. Correct? 02:50PM
A. Correct, as defined by the authors in this article.
Q. And I understand Mr. Rogers didn't highlight this for you, but the way the authors define the rate here is if you look at the footnote I have highlighted for you that the first number is the number of complications; second number is number of studies performed to evaluate complications. The number in the parenthesis, which I think was the rates you were discussing with Mr. Rogers, is the percentage of studies that showed complications. Did I read that more or less accurately? 02:50PM 02:51PM
A. You did.
Q. So what this is looking at, the Ferris article, is the percentage of studies that reported these types of complications, correct?
A. As I understand this article, because they were reviewing multiple filters with multiple data. 02:51PM
Q. But that would be different. That wouldn't be an apples to apples comparison to a clinical study where they were monitoring patients, for example, and seeing what the results with those particular patients were, right? 02:51PM

A. Well, I'm not sure I understand exactly your question.
Q. Let me phrase it in a more intelligible way.
This study that you were talking about with Table 2 is looking at the rate of complications reported based on the number of studies that they saw. It's a function of how many studies there are, right? 02:52PM
A. They use that, as you have highlighted, as their denominator.
Q. Okay. That's what the authors did?
A. Yes. 02:52PM
Q. Now, in this table, just while we have it up, that doesn't have any category for the phenomenon of migration -- I'm sorry -- the phenomenon of fracture and embolization of a filter component, right? That's not reported in Table 2?
A. Well, it's my understanding on this article, and we would have to probably look at the methods paragraph at the beginning to be sure, that they were creating categories, in this case they use the category of migration. And one must understand in fairness for any scientific study the authors make some decisions as to what their methods are, what categories they are going to be looking at and how they are going to list their data. I know this from having participated in studies myself. 02:52PM 02:53PM
Q. Understand. But what's not listed in here is the term embolization that we have heard about, right? That's not on Table 2? 02:53PM

A. You are correct in that they haven't used that particular medical term.

Q. Let's talk about what the SIR guidelines are not. Now, my understanding is that these guidelines are not intended to imply that the complication or trackable event rates that are set forth in Table 2 of the SIR guidelines are acceptable. That's not making a statement that as long as it's within these ranges that's an acceptable rate. Is that fair? 02:53PM

A. Certainly, personally, and I think I can speak for many of my colleagues, we would like there to be no complications and no adverse events for patients we treat. The SIR guidelines are meant to be educational, to summarize what is reported. And in your question with the use of acceptable, certainly we reported ranges of complications. And our intention was as stated explicitly in the guidelines text that if a particular doctor or someone working with IVC filters saw that they met or exceeded those numbers, then that would prompt their own personal review. 02:53PM 02:54PM

Q. So this is a tool for physicians, correct?

A. Well, it would be a tool for physicians, for practitioners, and for all of those who would work on the subject or with IVC filters. 02:54PM

Q. Well, the design of the study was to be helpful to practitioners who are implanting and removing IVC filters, correct? 02:54PM

A. No. I would say that the establishment of the guidelines was not limited to doctors or physicians alone in the same way it wasn't limited to interventional radiologists. Anyone who would be placing an IVC filter, working with patients with IVC filters, in fairness could read and benefit from the information contained in the guidelines. 02:55PM

Q. Let's see if we can agree on something. You would agree that the guidelines are not meant to establish a standard of care for physicians using IVC filters. Is that right?

A. They are meant to be educational. 02:55PM

Q. In other words not the standard of care. It's educational. It's information?

A. They certainly are guidelines, that's right, and a summary for physicians and those working with filters.

Q. And it's not meant to establish a standard of care for medical device companies who may be working with IVC filters, right? That's not its design? 02:55PM

A. Well, it's not for me to comment on what a company would or would not use as a standard. I can only say that as one involved in the guidelines our goal was to be informative, educational, and be helpful with the summary. 02:56PM

Q. But would you agree with the statement that SIR guidelines do not create safety thresholds for filters that relate to perforation, fracture, migration, tilt, or the inability to remove a filter? 02:56PM

A. Overall, I would.
Q. And that the SIR guidelines are not meant to be an instruction manual for medical device companies like Bard when they are designing a filter?
A. Certainly the guidelines were, as I think I have just described, any instruction manual or directives to the company would, of course, come from engineers and their own staff. 02:56PM
MR. CLARK: Gay, could you pull up Exhibit 6842.
Your Honor, in light of the Court's prior ruling concerning the SIR guidelines and their admissibility, I would move to admit 6842 into evidence. 02:57PM
THE COURT: What is it?
MR. CLARK: It is the update to the SIR guidelines.
THE COURT: The 2017?
MR. CLARK: Correct. 02:57PM
THE COURT: Any objection to having it admitted on the same basis?
MR. ROGERS: Your Honor, I do object. We admitted it for the purpose of the knowledge of the medical community in 2001 prior to the introduction of the Eclipse Filter. And as you just pointed out this was published in 2017. 02:57PM
THE COURT: Your response?
MR. CLARK: I was actually listening very carefully. I think Mr. Rogers established the same foundation that he laid for that in that this was published. It was disseminated to 02:57PM

physicians and physicians had notice. I think he used the words knowledge of it. So I think it's exactly the same analysis, Your Honor.

THE COURT: 4-20-17.

MR. CLARK: Correct. 02:57PM

THE COURT: So why is it relevant in this case? I think that was the objection.

MR. ROGERS: Correct, Your Honor.

MR. CLARK: Your Honor, I think it's relevant, and I can lay that foundation. It gets relevant into what has 02:58PM happened between 2001 and 2017. I would like to ask questions.

THE COURT: I think you need to lay additional foundation.

MR. CLARK: Okay.

BY MR. CLARK: 02:58PM

Q. In 2017 we had an update to the SIR guidelines, correct?

A. Yes.

Q. And that update also contains Table 2 like we saw in the last exhibit, right?

A. Yes. 02:58PM

Q. And Table 2 has the same type of information in terms of rates of failure that are collected from a category of information, right, of medical literature?

A. The Table 2, that's true, is a very similar table.

Q. And if you could pull up Table 2 in 6842. 02:58PM

Do you see the disclaimer in the bottom of Table 2 that is highlighted sir, or Doctor?
A. Yes.
Q. It says -- well, and does that indicate that these are reporting outcomes that are collected from data but are not the SIR standards for complications? Is that fair? 02:59PM
A. It would be fair to say that these, again, as we discussed earlier, are presented as information as a summary. And it says simply the statement and the sentence that you just read.
Q. And so physicians who have received this would now know, at least as of 2017, that these are not meant to be representative of the SIR standard for complications. Is that fair? 02:59PM
A. I think you would have to clarify that question for me because I'm not exactly sure of the meaning of your question.
Q. Right. You said that doctors get this article, right? It's a peer-reviewed publication? 03:00PM
A. Yes.
Q. And when doctors get that information, presumably they read it. Right?
A. Yes. 03:00PM
Q. And in reading it, they would learn that it would be very clearly expressed that the design of this information is not to be representative of the SIR standard for complications. Right?
A. Well, the SIR, I think, has been very appropriate in 03:00PM

calling these guidelines. The SIR, as you know, is a professional organization. It is not a regulatory or standards body so in that regard, the charge of the SIR, as an institution, would not be to create some form of regulatory standard. 03:00PM

MR. CLARK: Your Honor, I believe that makes it relevant, particularly to how the SIR guidelines are being used in this particular case in 2018.

MR. ROGERS: No objection, Your Honor.

THE COURT: All right. I'm going to admit 6842 with the same limiting instruction it's not for the truth of the matter asserted, simply regarding notice and knowledge within the medical community. 03:01PM

MR. CLARK: Gay, if you could back up.

May I publish this, Your Honor? 03:01PM

THE COURT: Yes.

MR. CLARK: Before you back up, Gay, that's the footnote that I was referring to the disclaimer at the bottom of Table 2?

THE WITNESS: Yes. And could you repeat that, please? 03:01PM

BY MR. CLARK:

Q. What is highlighted at the bottom, just for the benefit of the jury, is the disclaimer we were just discussing?

A. That's correct.

Q. If you could go to Page 2, please. Doctor, I have 03:01PM

highlighted some text here. And it says: Although retrievable filters are often placed as permanent devices, the long term safety and efficacy of these devices as a class have not been established.

Do you agree with that statement? 03:02PM

A. I would have to give a cautious commentary on that statement, and if you like I can elaborate.

Q. Your Honor -- or Doctor, I have limited time with you so I'm sure Mr. Rogers will bring that out. But what I'm asking is yes or no, do you agree with that statement from the SIR? 03:02PM

A. Well, and my answer to try to be as fair as I can in answer to your question is I actually can't answer this as a yes or no. The long term safety and efficacy of these devices as a class is something which is continually looked at in studies. It has been reviewed in the previous two SIR annual meetings 03:02PM with abstracts and publications. And if you would like I can even comment on some of these which I saw a year ago.

Q. Let me ask this question: As of 2017, when this SIR guideline update was published, the opinion of the authors was that the long term safety and efficacy of retrievable filters 03:03PM had not yet been established.

Is that fair?

A. I would say certainly, this is the considered opinion of the authors in this publication. Yes.

Q. That's what I was asking. Thank you. 03:03PM

A. Correct.
Q. Now, perhaps to speed -- we talked a little bit about the cascade, and that's a term that you are not -- you have not seen literature to support that term. Is that correct?
A. Correct. 03:03PM
Q. And you haven't seen literature to talk about the kind of constellation of problems that could happen with migration leading to tilt to perforation to fracture. Is that fair?
A. I have either heard alluded to, or at least I'm aware of individuals who have referred to this. And again, I can 03:03PM
elaborate as to who those are and what types of studies. But in my opinion, to date there has not been a sequence of events which, in my view, has shown a proof to those statements.
Q. And my question was specific to literature, so I would appreciate if you could just respond to the question I asked. 03:04PM
A. Uh-huh.
Q. As literature you have not seen that. That's what you told Mr. Rogers, right?
A. That I have not seen what, please?
Q. Literature referring to the cascade of events that we 03:04PM
described.
A. As I mentioned, I have heard a sequence of events referred to, not specifically the word "cascade." And I, in proceedings I have heard this referred to, to answer your question.
Q. In terms of -- let me make sure I understand. So you 03:04PM

haven't received any internal documents from Bard that talk about Bard's understanding of the relationship between migration, tilt, perforation, and fracture. Is that fair?
A. That's correct. I haven't received any proprietary or internal company documents. 03:05PM
Q. And if Bard understood that there could be that cascade of information as reflected in its internal documents, that's not information you have been given in this case. Fair?
A. Well, that would be a hypothetical question. As I mentioned, I haven't received any such documents so it's really 03:05PM not possible for me to comment on that subject.
Q. And in terms of you haven't been given analysis or data or internal information from Bard about fracture rates with the Eclipse Filter. Is that fair?
A. That's fair. I have not received any internal documents 03:05PM from Bard on that particular subject.
Q. And the information you told Mr. Rogers was from looking -- when you talked about the articles that were referenced in the Ferris article, that those fractures -- I'm sorry, not the Ferris article -- in the Table 2 of the 2007 update, there were 03:06PM no Eclipse fractures represented in that data. Correct?
A. That's correct.
Q. Your understanding of that was based on reviewing headlines of data, of articles. That's what you told us?
A. I have seen those articles, over the years have been 03:06PM

familiar with them, and have probably read them either in whole or in part in the course of my work.
Q. But what you told us earlier was that you read the headlines. Did I hear that wrong?
A. No. That's not accurate. If I remember the question correctly, what was asked of me is if I have seen the articles and I said that I have seen the titles and am aware of all the articles. I would not presume to testify that I have read every word of each one of those articles. But yes, I am largely familiar with them and have reviewed all of those citations that were asked of me a little bit earlier. 03:06PM 03:06PM
Q. In the interest of time I have prepared a sort of side-by-side comparison of the two tables from the 2001 and the 2016 study.
MR. CLARK: Your Honor, may we be permitted to put that on the ELMO to display? 03:07PM
THE COURT: Just to the witness?
MR. CLARK: To the witness. That would be fine.
THE COURT: All right. Yes.
BY MR. CLARK: 03:07PM
Q. Can you see that, Doctor?
A. Yes, I do.
Q. And in 2001, just a to run through this again, IVC penetration reported rates were 0 to 41, right?
A. Yes. 03:07PM

Q. Migration was 0 to 18?
A. Yes.
Q. And filter fracture was 2 to 10, right?
A. Yes.
Q. And fast forward to 2016, which is when the data was collected for the 2017 study, we have IVC penetration was 0 to 100, right? 03:07PM
A. Yes.
Q. And migration of filter now includes the category like Mr. Rogers said, filter components, right? 03:08PM
A. Yes.
Q. This introduces this concept of fragment embolization that we talked about earlier?
A. That's fair.
Q. And the reported rates for that were 0 to 25, right? 03:08PM
A. Yes.
Q. And for filter fracture was 0 to 50?
A. As listed on your chart, yes.
Q. So what we know from this comparison is that once retrievable filters are part of the population that is studied, the upward bounds of these ranges goes up considerably. Is that fair? 03:08PM
A. I will say that as represented by the numbers on your charts, those numbers have increased as we're seeing them in front of us. 03:08PM

Q. And they increased across each of those three categories, correct?
A. In each of the categories of your chart the numbers have increased.
Q. And we also now have a recognition of the phenomenon of fragment embolization in the 2016 study, correct? 03:08PM
A. Well, no. Let me comment on that, if I may.
Q. I'm going to ask you a yes or no question. Is that related in the 2016 study?
A. The question that I believe you just asked me is that it represented -- did it represent a new concept of distal embolization. That's not a new concept. In fairness, counselor, embolization of filter fragments have been recognized as far as back as 1972. And I have had colleagues and I have had my own personal experience where I have seen 03:09PM either fractures or portions of filters that have then gone on to a nontarget organ.
MR. CLARK: Move to strike as nonresponsive, Your Honor.
THE COURT: Granted. The jury should disregard the 03:09PM last answer.
BY MR. CLARK:
Q. Doctor, the definition of filter embolization in the Exhibit 7312, which are your guidelines, is post-deployment movement of the filter to a distant anatomic site completely 03:10PM

out of the target zone. Is that right?
A. That's correct.
Q. And the definition of filter embolization, when we fast forward to Exhibit 6842, is post-deployment movement of the filter or its components to a distant anatomical site completely out of the target zone. The only difference between those is we now include "or its components," is that right? 03:10PM
A. No. I think one must be pretty careful. It's a matter of medical semantics here whether the particular person in the particular study is talking about movement of the filter as a whole therefore using the word embolization, which is in the interventional radiology community the definition. And it's important to understand that when a portion that is less than the total filter goes to an area, let's say such as a pulmonary artery or distal pulmonary artery, that that, in the second guidelines, was referred to as an embolization. I think of that myself as a component embolization, and I can elaborate further if you wish. 03:10PM 03:11PM
Q. I do not wish. I would move to strike as nonresponsive.
THE COURT: I think that one was responsive. But let's say this. If you want him to answer yes or no, then Doctor, either answer yes or no or simply say you can't answer it yes or no. And if he wants elaboration he'll call for it. 03:11PM
THE WITNESS: Yes.
BY MR. CLARK: 03:11PM

Q. Doctor, did the definition change for the 2016 for filter embolization?
A. The question you asked I actually can't answer.
Q. You can't say whether there was a difference between the 2001 and the 2006 definition of filter embolization? That's yes or no? 03:11PM
A. I cannot say that because I would have to compare the specific medical semantics. In fairness, what I can say is what I have told you is my --
THE COURT: That's good, Doctor. You said you can't answer. 03:12PM
MR. CLARK: Telling me no, right?
THE WITNESS: Thank you.
BY MR. CLARK:
Q. In terms of rates, Doctor, if there was a physician who reported to Bard fracture embolization, that he experienced five patients that he examined and wrote an article about all five, each with a different failure mode, the rate would be -- let me withdraw that question. I think -- I don't think I understand the note from my counsel. 03:12PM
Doctor, you are not an engineer, right?
A. No. I do not have training of an engineer.
Q. And you haven't done a failure modes effect analysis on IVC filters, is that fair?
A. I have worked with various engineering aspects in the 03:13PM

course of looking at filters as a study, but no, I have not done failure mode engineering analysis on the Bard or other IVC filters.

Q. Thank you, Doctor.

THE COURT: Redirect? 03:13PM

MR. ROGERS: Very briefly, Your Honor.

REDIRECT EXAMINATION

BY MR. ROGERS:

Q. Dr. Grassi, in the course of your career as a medical doctor, have you ever received internal company documents to 03:13PM evaluate for the manufacture of any medical device that you use?

A. No, I have not and have not requested them either in an effort, for example, during the guidelines to remain impartial.

Q. When you were preparing the guidelines that were published 03:13PM in 2001, did your committee consider any internal documents of any company as a source of information for those guidelines?

A. That's a very reasonable question, and that was a question that we considered whether to dig down, so to speak, and look at very specific information from the companies. We did not do 03:14PM that for a variety of reasons, which included the fact that the majority of the committee members felt it was most fair and most impartial for us not to favor or give the appearance of favoring any one particular company or group, but rather that it would be the most accurate for us to comment on what was in 03:14PM

the literature and what was out there in practice in the community.

Q. Thank you. No further questions.

THE COURT: All right. Thank you, sir. You can step down. 03:14PM

If you want to stand up, Ladies and Gentlemen, feel free to do that while we're bringing in the next witness.

MS. HELM: Your Honor, at this time we call Andrzej Chanduszko.

THE COURTROOM DEPUTY: Sir, please come forward and raise your right hand, please. 03:15PM

(The witness was sworn.)

THE COURTROOM DEPUTY: Could you please state your name and spell it for the record, sir.

THE WITNESS: My name is Andrzej Chanduszko. 03:15PM
A-N-D-R-Z-E-J, and the last name is C-H-A-N-D-U-S-Z-K-O.

ANDRZEJ CHANDUSZKO,

called as a witness herein, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. HELM:

Q. Good afternoon, Mr. Chanduszko.

A. Good afternoon.

Q. Would you please tell the ladies and gentlemen of the jury where you work? 03:16PM

A. I work at Bard Peripheral Vascular.
Q. How long have you worked at -- I'm going to call it BPV. How long have you worked at BPV?
A. I worked there for 14 years.
Q. What type of products does BPV develop and manufacture? 03:16PM
A. Products, lots of implantable devices such as vena cava filters, stents, skin grafts, angioplasty balloons, biopsy needles. These are some of them.
Q. Are you an engineer by education and training?
A. Yes, I am. 03:17PM
Q. Mr. Chanduszko, where were you born?
A. I was born in Poland.
Q. And what year did you come to the United States?
A. In 1989.
Q. And I'm not going to ask you your birthday but how old were you in 1989 when you came to the United States? 03:17PM
A. I was 24 years old.
Q. And did you become a U.S. citizen?
A. Yes, I did.
Q. Is English your first language? You speak with an accent, obviously. 03:17PM
A. No, it is not. Polish is my first language.
Q. Do you still have to -- do you still struggle with English phrases and terms sometimes?
A. A little bit sometimes, yes. 03:17PM

Q. And personally how do you manage that when you are having to translate phrases or terms?
A. So I guess that depends on the environment. But in a professional environment I typically try to reduce, you know, the terms to something that is more defined, more technical. 03:18PM
Q. And is it sometimes easier for you to speak in technical terms?
A. Yes. Sometimes it is.
Q. Would you describe your education for the jury, please?
A. So I started four years in Poland, I started environmental protection. And when I came to the United States, I studied mechanical engineering at Northeastern University in Boston, and I have a Bachelor of Science degree. 03:18PM
Q. Why did you choose to become an engineer?
A. So I always wanted to be an engineer since I was a child. And once I went to school, physics and math were my favorite subjects, and I always liked problem solving. So it became very natural for me to do engineering things. 03:18PM
Q. After you moved to the United States, did you have a job at Massachusetts General Hospital? 03:19PM
A. Yes, I did.
Q. And what were you doing at Massachusetts General Hospital?
A. I was delivering medical equipment and supplies to the whole hospital. It's a huge hospital and in different buildings. 03:19PM

Q. And in the process of delivering those medical supplies and equipment, were you able to observe different and new medical technologies?
A. Yes, I did.
Q. And how did your work at Mass General in delivering medical supplies and equipment impact your career decisions? 03:19PM
A. So this is the first time in my life I worked in a hospital, and I worked there for a few years. And, you know, while I was delivering the equipment, not just equipment, bed frames and other things like that, I would set it up for patients. And I was able to observe a lot of suffering and different diseases. At the same time, I also saw how modern medicine, modern technology, how it can positively affect these patients. 03:20PM
Q. And did you decide to try to work in the medical device field as a result of that? 03:20PM
A. Yes. So that really -- I really wanted to help. And when I went to school, I was studying mechanical engineering, I asked my co-op advisor to get me in touch with a medical company so I can interview with them. 03:20PM
Q. Have you spent the majority of your professional career since college involved in the medical device industry?
A. Yes. 100 percent.
Q. Mr. Chanduszko, do you own any patents?
A. Yes, I do. 03:21PM

Q. How many patents do you have?
A. I have currently over 70 patents.
Q. Are they for more than one type of product?
A. Yes. They cover many different products.
Q. We're here today about an IVC filter. What percentage of your patents relate to IVC filters? 03:21PM
A. So I don't know the exact number, but I think it's going to be about a third.
Q. Now, after you graduated and received your mechanical engineering degree, did you start working for a company called NMT? 03:21PM
A. Yes. That's correct.
Q. And when did you join NMT?
A. So as a full time employee, that was in 1997.
Q. Did you do a co-op or an internship before you became a full time employee? 03:21PM
A. Yes. So when I mentioned earlier, I asked my co-op advisor to get me in touch with a medical company, and in fact she did. And I interviewed, and they hired me, so this is a more of a temporary job for students but it's a full time job for six months. And when I graduated they offered me a job and hired me full time. 03:22PM
Q. When you started at NMT, or during your work at NMT, did you eventually work on what is now known as the Recovery Filter? 03:22PM

A. That's correct.
Q. The design and the development of the Recovery Filter actually started at NMT, right?
A. Yeah. So because it was my first job after school, I was working under the direction of more senior engineers, and one of the projects was the Recovery Filter. 03:22PM
Q. And since your work at NMT through today, are you familiar with what diseases IVC filters are intended to treat?
A. Yes. They prevent pulmonary embolism.
Q. And based on your understanding of what you have learned over the past decades working on IVC filters, do you have an understanding that pulmonary embolisms are potentially deadly? 03:23PM
A. Yes. According to different estimates, it's about 50 to 200,000 people die every year in the U.S. alone.
Q. Now, we have heard some testimony about the risks of IVC filters. Through your experience in working on IVC filters, do you understand that there are inherent risks associated with the use of IVC filters? 03:23PM
A. Yes. That is correct.
Q. And what is your job as far as attempting to reduce those risks? 03:23PM
A. So there's different parts, but one is trying to understand the environment; two is designing tests and building prototype and testing the filters, making sure they meet all the requirements for the filters. 03:24PM

Q. Is it your goal to reduce the risks and complications as much as possible?
A. Yes. That's correct.
Q. And when you go to work every day, is that your goal when you are working on IVC filters or any medical device? 03:24PM
A. Yes, it is.
Q. Now, we're here today about an Eclipse Filter, which is the device that was implanted in Ms. Jones. But over the last several days, this jury has also heard a lot about the Recovery Filter and the G2 Filter. 03:24PM
What is the relationship between the Recovery Filter and the G2 Filter?
A. So the Recovery Filter was the first generation IVC retrievable filter that was developed at NMT Medical, and then the G2 Filter was the second generation of the Recovery Filter 03:24PM that was developed at Bard.
Q. Okay. So we started out and we learned a few minutes ago that the Recovery Filter actually started at NMT. Is that right?
A. That is correct. 03:25PM
Q. And NMT eventually sold its rights to the Recovery to Bard, is that correct?
A. Yes.
Q. Did you eventually move from NMT to Bard?
A. Yes. I did move in 2004. 03:25PM

Q. And when you moved to Bard, did you have the opportunity to continue to work on the IVC filter, the Recovery Filter?
A. So it was the G2 Recovery Filter.
Q. Okay. At NMT, what was your role in the development of the Recovery Filter? 03:25PM
A. So my main role was to test the filters.
Q. And did you do more than one test? Did you run various tests?
A. Yes. So there were multiple different tests, a whole battery, in fact. And some of them were already developed and 03:25PM some of them needed to be developed.
Q. And was it part of your role to help develop tests for the Recovery Filter?
A. Yes. That's correct. Some earlier versions, but yes.
Q. What is design verification and validation? 03:26PM
A. So during the development of a medical device, typically there's a number of different phases. We start with the concept, which is more of a prototyping, the feasibility which is a little more formal, and then design verification and validation test is the final formal test that is then submitted 03:26PM to FDA.
Q. So you have a concept or an idea, you do a feasibility analysis, and then you do design verification and validation to see whether the concept and the feasibility are going to work. Is that right? 03:26PM

A. So concept typically start with prototypes, and these prototypes are developed further, fine-tuned. And in feasibility, typically there's one design that is selected that is tested, a large assemble size and then the V&V test, it tests large sample sizes of implants for statistical significance. 03:27PM

Q. That process from concept to design validation and verification -- I said it backwards -- design verification and validation, is that something that happens in a matter of weeks or months? 03:27PM

A. No. It typically takes some years.

Q. And after a product has gone to market, for example, after the Recovery Filter went to market, does the design evaluation process end? Is that it?

A. No. That's not it. 03:27PM

Q. Is there continued review and analysis of the design based on information received from the market?

A. Yes. That's correct.

Q. Are you directly involved in that process?

A. Typically not. 03:28PM

Q. So your role is the design verification and validation before the product goes to market. Is that right?

A. Yes. So there's a different department that typically attracts the filter performance after the launch, and these results are shared with a team that's working on new devices. 03:28PM

But I wouldn't be directly involved, I would be indirectly involved in the matter of this monitoring of filter performance is shared later with engineers so they can work on many improvements.

Q. Once the concept and the feasibility of the Recovery Filter were completed, what types of tests did NMT perform? 03:28PM

A. So there were many different tests. I can probably break them into three different categories. So one was what we call bench testing; another one is animal testing; and the final one is clinical trial. 03:29PM

Q. And when you refer to the term "bench testing," what are you talking about? Is that laboratory testing?

A. Yes. So that testing is done in a laboratory.

Q. And what's the purpose of bench testing or laboratory testing? 03:29PM

A. So typically, engineers have a little more control and more repeatability when it comes to these tests so they can do -- test many more filters and they can do statistical calculations and they can challenge the filters in all kinds of different ways. 03:29PM

Q. In your experience as an engineer who has worked in the medical industry for your entire career, are these bench tests or laboratory tests the types of tests medical companies start with and rely on?

A. Yes. That is an industry standard. 03:30PM

Q. Was one of those laboratory tests or bench tests that you performed, or one type of them, a fatigue test?
A. That's correct.
Q. Did you also perform bench testing or laboratory testing for migration resistance? 03:30PM
A. Yes.
Q. Have you personally designed any bench test methods for IVC filters?
A. Yes. I design a number of them.
Q. Is that an easy concept to mimic the dynamics of the IVC? 03:30PM
A. So it depends on the test, and some tests are not too bad but some are very difficult to design.
Q. And why is it? Why is that difficult?
A. So the cava typically behaves in a reasonably predictable manner but at times it can be a very dynamic and very harsh 03:31PM environment. And one of the difficulties is that it is sometimes extremely difficult or even impossible to observe these rare events.
Q. Does Bard know everything about the dynamics, everything about the inferior vena cava? 03:31PM
A. No. It's impossible to know everything.
Q. Does any medical device company manufacturing IVC filters know everything about the inferior vena cava?
MR. STOLLER: Objection, Your Honor. Foundation.
THE COURT: Hold on just a minute. 03:31PM

MS. HELM: I will rephrase it, Your Honor.
THE COURT: All right.
BY MS. HELM:
Q. Is it possible for a medical device company such as Bard to know everything about the inferior vena cava? 03:31PM
A. No. It's not possible.
Q. Based on your experience in your review of medical literature and your experience in designing IVC filters for your entire career, does the medical community, is it your understanding whether the medical community knows everything 03:32PM about the dynamics of the IVC filter?
MR. STOLLER: Objection, Your Honor. Foundation.
THE COURT: Overruled.
BY MS. HELM:
Q. Go ahead. You can answer. 03:32PM
A. No, they don't.
Q. So even though NMT and then Bard didn't know everything about the dynamics of the IVC when it was designing the Recovery Filter, why put the filter on the market?
A. So one answer to it is that the performance of the filters, 03:32PM the filters, they have been around since 1970s. And people may not know absolutely everything about the vena cava, but they can typically tell with reasonable accuracy how they are going to perform. Because typically, the designs, the new designs that are coming are typically tested against proven designs 03:32PM

that are already on the market.
Q. Was it important to you when you were working on the Recovery Filter to be able to put a filter on the market that could be retrieved?
A. Yes. Absolutely. 03:33PM
Q. Did you feel like you were bringing a lifesaving device to the market?
A. Yes.
Q. Was that important to you personally and professionally?
A. It is important. That's why I'm in the medical field, to help people. 03:33PM
Q. Let's go back and talk about the testing. What types of animal testing did NMT perform on the Recovery Filter?
A. So for this type of filter, which is a retrievable filter, typically, the work involves -- so there are medical doctors who perform these tests, and typically, these tests are done in a larger animal, a sheep, for example, would be one example, because they have vena cava that is similar to human. And the doctors would typically implant the filters and judge the performance of the filter during implantation. 03:33PM 03:34PM
Then the filters would be implanted for weeks or months. And during that time, the doctors would also monitor the performance and finally, the filters were retrieved by the doctors and they would then judge how the filter performed and also how easy it was to take it out. And finally, the vena 03:34PM

cava would be sent for analysis to another doctor which would be histopathologist.
Q. Did NMT also conduct a clinical study with Dr. Asch on the Recovery Filter?
A. Yes. That's correct. 03:34PM
Q. Now, I want to talk a little bit more about this testing and the testing that you were involved with on the Recovery Filter. Were there hundreds of tests run on the Recovery Filter before it went to market?
A. Yes. Very likely, yes. 03:35PM
Q. And out of the interest of time and for the benefit of the jury, we're not going to go through hundreds of tests. But I do want to talk to you about fatigue testing. Were you involved in the fatigue testing of the Recovery Filter?
A. Yes. I was personally involved. 03:35PM
Q. What is fatigue testing?
A. So fatigue is a consideration for a medical device, particularly an implantable device. It has to do with a phenomenon that if a metal in this case is deformed many, many times it can weaken to the point where it can break. So the 03:35PM test is designed to deform the material and make sure that the material does not break over the effectively intended implantation time of the filter.
MS. HELM: Scott, would you pull up 5233, please.
BY MS. HELM: 03:36PM

Q. Mr. Chanduszko, can you see that on your screen?
A. Yes, I can.
Q. Would you please tell the Ladies and Gentlemen of the jury what this document is?
A. So this is a standard operating procedure for the fatigue test that was done on the Recovery Filter. 03:36PM
Q. This is your test method. This is how to run the test, is that right?
A. Yes. That's correct.
MS. HELM: Your Honor, at this time I would move for the admission of Exhibit 5233. 03:36PM
MR. STOLLER: No objection.
THE COURT: Admitted.
MS. HELM: Your Honor, may I publish it to the jury?
THE COURT: Yes. 03:36PM
MS. HELM: Would you go ahead and turn to Page 2?
BY MS. HELM:
Q. Mr. Chanduszko, would you describe the test that is laid out in Exhibit 5233?
A. So the purpose of the test was to accurately evaluate 10 years equivalence of corrosion and fatigue endurance of 16 Recovery Filters by inducing a cyclic stress state in a simulated physiological environment. The duration of the experiment was equivalent to 10 years of pulmonary output, or 32 million cycles. 03:37PM

Q. Why 10 years? Why did you choose 10 years?
A. So we really didn't choose 10 years. This is, I believe, this is a FDA guidance and this is also an industry standard for most of the implantable devices.
Q. And you said it's 10 years of pulmonary outlook, which is approximately 32 million cycles. Is that right? 03:37PM
A. Yes. That's correct.
MS. HELM: If you pull up 5234, please.
BY MS. HELM:
Q. Can you see that Mr. Chanduszko? 03:38PM
A. Yes, I do.
Q. Would you please tell the Ladies and Gentlemen of the jury what this document is?
A. So this document was created after the completion of the test. 03:38PM
Q. These are the test results?
A. Yes. These are the test results. That's correct.
Q. You had the test procedure, which we previously saw, you ran the test, and these are your results. Right?
A. Yes. That's correct. 03:38PM
Q. And were you personally involved in compiling these test results?
A. Yes, I was.
Q. And is that your signature on the first page of Exhibit 5234? 03:39PM

A. Yes, it is.

MS. HELM: Your Honor, at this time I would move for the admission of Exhibit 5234.

MR. STOLLER: No objection.

THE COURT: Admitted. 03:39PM

MS. HELM: May I publish it to the jury, Your Honor?

A JUROR: Your Honor, we already saw it. It was already up on the screen.

THE COURT: Okay. It's in front of them now.

MS. HELM: Would you turn to Page 5234.002, please. 03:39PM

This report states in the first paragraph -- Scott, can you pull that out?

BY MS. HELM:

Q. Pulmonary functions produce a measurable diameter change of about one millimeter. Is this distension, this measurable IVC 03:39PM diameter change?

A. I'm sorry. Could you repeat?

Q. Sure. In the highlighted section it talks about it produces a measurable IVC diameter change of about one millimeters. Is that the distension of the IVC? 03:40PM

A. Yes. That is the distension.

Q. What pulmonary functions, what's going on in the body that produces this change or distension of the IVC?

A. So the pulmonary function is effectively breathing in and breathing out. And this produces a measurable change in the 03:40PM

cava diameter, or the cava distends and compresses.
Q. As I stand here today breathing in and breathing out, my IVC is widening and contracting. Is that right?
A. That is correct.
Q. The document also refers to a corrosive environment. Why is the IVC a corrosive environment? 03:40PM
A. So it's not very corrosive, but the blood in the vena cava has all kinds of salts and effectively with the salt and metal this is something that you always want to evaluate.
Q. So in your testing you take into consideration the fact that the material flowing through the IVC is blood and it contains with it salts and other materials. Is that right? 03:41PM
A. That is correct.
Q. Would you please turn to Page 4. And what is this, Mr. Chanduszko? 03:41PM
A. I'm sorry. It is the graph or --
Q. I'm sorry. We need the test results.
Are those the results, Mr. Chanduszko?
A. That's correct. These are results.
Q. And you mentioned previously 36 million cycles. What does that mean? 03:41PM
A. So the 36 million cycles, so the requirement, the guidance is, as I mentioned, is 10 years equivalency of pulmonary, which is breathing. So that 10 years need to be converted to a number of cycles. And the number of cycles that were 03:42PM

calculated, it is my recollection that it was 32 million cycles would be the equivalent. And then I believe we ran the test to 36 million cycles just to make sure we passed the 32 million mark.

Q. And after you ran the test to 36 million cycles, did you make a determination of whether the filters, the Recovery Filters that you tested had passed this fatigue test? 03:42PM

A. Yes. That was the requirement per the protocol and that's what we did.

Q. And did they pass the test? 03:42PM

A. Yes, and they passed the test.

Q. And after you performed the test on it did you inspect the filters?

A. Yes.

Q. And did you find any evidence of cracks, deformation, fracture, or any other damage in those filters? 03:43PM

A. No. There was no sign of any damage.

Q. In your mind as an engineer, was this a reasonable test to perform in order to understand the fatigue performance of the Recovery Filter in an IVC? 03:43PM

A. That was a very reasonable test.

Q. Now, after you cycled it, you kept running it, is that, for the 32 million you kept running it. Is that right?

A. That is correct.

Q. Why did you do that? If it passed the test, why did you 03:43PM

keep running it?
A. So the team wanted to go above and beyond just to make sure that the device was robust.
Q. And as you kept running it, do you recall how far you ran it or how many cycles? 03:43PM
A. So my recollection is that we passed 400 million cycles.
Q. So the standard was 32 million cycles but you ran it to 400 million cycles, is that right?
A. That's correct.
Q. And it still passed, is that right? 03:44PM
A. Yes. That's correct.
Q. Now, you have talked about this test, and I'm assuming this didn't take place over a matter of hours or days. This took some weeks to run?
A. Yes. So it was a long time ago but I think it was about 03:44PM six months.
Q. And did you keep track of the test as it was going along and the results that you were receiving?
A. Yes. So there were measurements frequently taken because we had to measure the simulated vena cavas where the filters 03:44PM were implanted to make sure that we are getting at least one millimeter distension. So over the six months we were taking the measurements, at least one once a week, probably more frequently than that.
Q. Did you record that information in lab notebooks for the 03:45PM

test?
A. Yes. That's correct. The results of these were -- all monitoring was recorded in the notebook.
Q. And I'm just going to hold this up. I'm not going to move to admit it. Is this a lab notebook for the fatigue test that we are talking about? 03:45PM
A. Judging by the cover, yes, that's what it is.
Q. And in this there are just pages and pages of test results and calculations and information and data that you recorded throughout the course of the test, is that right? 03:45PM
A. That is correct.
THE COURT: Does that have an exhibit number, Ms. Helm?
MS. HELM: Yes, it does, Your Honor. It's 5022.
THE COURT: All right. 03:45PM
BY MS. HELM:
Q. For each test that was run on the Recovery Filter is there a comparable set of compilations and data that was recorded and analyzed throughout the process of the test?
A. So every test that was performed there was data collected. 03:45PM Obviously this test ran over many, many months so it was probably a little more data on this test than the other ones. But typically there's pages and pages of notebook data for every test.
Q. And that's what you analyze and have available to you to 03:46PM

determine both whether the test is working and whether the product is passing the test correct?
A. That's correct.
Q. Let's shift gears and talk about the G2. At some point after the FDA cleared the Recovery you were at Bard and Bard started working on the next generation the, G2. Is that right? 03:46PM
A. That is correct.
Q. What was the goal or the purpose of designing the G2 Filter?
A. So the two major goals as I remember was to improve fracture resistance and migration resistance. 03:46PM
Q. So the Recovery Filter was on the market, and you were receiving information from the market there were some incidence of fracture, is that right?
A. Yes. What I mentioned before, there's a team that monitors all these events and these events are shared with what we call the filter team. 03:46PM
Q. And you also mentioned movement. What was the movement or migration of the Recovery Filter that you were trying to address were the G2? 03:47PM
A. So that was the movement up.
Q. So up?
A. Yes.
Q. And we have heard that referred to as cranial migration. Is that a term that you used? 03:47PM

A. Yes. Cranial migration. That's the term.
Q. And why did you want to reduce the fractures or the incidence of fractures from the Recovery to the G2?
A. Because fractures can occasionally lead to complications and therefore, we wanted to eliminate them or at least minimize them. 03:47PM
Q. Same reason for the attempt to reduce cranial migrations?
A. That's correct.
Q. What was your role in the process of developing the G2 Filter? 03:47PM
A. So I did many different things as an R&D engineer, including building and manufacturing fixtures to make these filters, making filters, testing filters, designing test methods. That probably captures most of it.
Q. Did the G2 go through this same design process that we talked about with Recovery from concept to feasibility to verification and validation and then before it could go to the market? 03:48PM
A. Yes. That's correct.
Q. You mentioned that you used different prototypes for testing of the G2. Why did you do that? 03:48PM
A. So we used many different prototypes, and effectively you start with the hypothesis. You want to improve a particular characteristic and you design a prototype for that and then you have to test it. And typically, we make different changes to 03:48PM

different degrees, and based on that we want to see what is the effect so we can fine tune the design to give us the performance that, you know, the best performance that we can achieve.

Q. When you are designing any IVC filter and when you were designing the G2, did you have to balance the different attributes of the filter in order to create the best filter reasonably possible? 03:49PM

A. Yes, because often times the requirements are contradictory, and in the end a lot of it is a balancing act. 03:49PM

Q. So you may be able to address one complication but then you have to worry about whether it's creating or increasing another complication?

A. Yes. That could be the case.

Q. And that's something you knew when you were designing IVC filters? 03:49PM

A. Yes. That is true for any medical device.

Q. Okay. And that's something you take into consideration and you look for in your testing and your test results, correct?

A. Yes. That's correct. 03:49PM

Q. Did you make, as part of the design team, did you make significant changes from the Recovery to the G2 Filter?

A. So, geometry-wise, the filters were very similar. But performance-wise, we did make very significant changes.

Q. At my request, have you prepared a demonstrative or a 03:50PM

picture to show the differences between the Recovery and the G2?
A. I'm sorry?
Q. At my request, did you prepare a demonstrative to show the differences between the Recovery and the G2? 03:50PM
A. Yes.
Q. Would that help you explain those differences to the jury if we were able to put those pictures up?
A. Yes. Absolutely.
MS. HELM: Would you please pull up 7875? 03:50PM
Your Honor, may I display this to the jury as a demonstrative only?
MR. STOLLER: I'm sorry. May I look at it for a moment, Your Honor? It hasn't been disclosed to us.
Perhaps with a bit more foundation, I'm not sure this 03:51PM accurately depicts what it purports to depict.
THE COURT: Would you lay that foundation, please, Ms. Helm.
MS. HELM: Sure.
BY MS. HELM: 03:51PM
Q. Mr. Chanduszko, does this document show a diagram of the Recovery Filter and specifically certain aspects of the Recovery Filter that are at the bottom of the longer legs of the filter?
A. So I'm sorry. I'm not sure. If you could rephrase. 03:51PM

Q. Does the diagram in front of you depict a Recovery Filter?
A. Yes. The part on the left is Recovery.
Q. And does the diagram also depict a G2 Filter and show certain changes to the G2 Filter as compared to the Recovery Filter? 03:51PM
A. That's correct.
Q. And would you go ahead and go to the second page, please. And on the second page of the diagram, does it again show differences between the Recovery Filter and the changes you made to create the G2 Filter as far as measurements of those 03:52PM filters?
A. Yes.
Q. And would you go to the next page, please. And does Page 3 of the diagram show additional changes made from the Recovery Filter to what was eventually called the G2 Filter as it 03:52PM relates to certain aspects or components of the filter?
A. That is correct.
Q. And would you go to Page 4, please. And on Page 4, does the diagram show differences that were made between the Recovery Filter and the G2 Filter at the cap or the top of the 03:52PM filter?
A. Yes.
Q. And would you go to the last page, please.
And does the last page also show geometric differences and angle differences between the Recovery Filter and the G2 03:53PM

Filter?
A. Yes, it does.
Q. Would it be helpful for you to be able to describe these pictures, rather than me describing them, for you to describe them to the jury to show the differences between the Recovery and G2? 03:53PM
A. Yes, I believe so.
Q. Your Honor, I would ask to publish this as a demonstrative exhibit.
MR. STOLLER: Now that I have seen it we have no objection, Your Honor. 03:53PM
THE COURT: Okay. You may.
MS. HELM: Scott, would you go back to the first page, please.
BY MS. HELM: 03:53PM
Q. Mr. Chanduszko, would you describe to the jury what is shown here on the first page? Start with the Recovery and explain the hooks on the bottom and then explain the differences between the Recovery and the G2 as they are depicted on this page. 03:53PM
A. So the image on the left shows the Recovery Filter, which is the first generation of retrievable filter. The image on the right shows G2 Filter, which is the second generation of the Recovery Filter. So this is the filter that was developed at Bard. 03:54PM

And I'm just going to go over maybe kind of a naming scheme. So the top of the filter, we call it a tip, looks like a rounded cylinder. Then what you have is the longer parts, the wires, that end with hooks. We call these legs. And then the shorter ones that are bent roughly halfway through, we call these arms. And then the area right under the tip, we call it a neck. 03:54PM

So in this image what you see is the G2 Filter had stronger elastic hooks, so the hooks of the Recovery Filter were modified to make them stronger. Also the arms on the G2 Filter are longer and curved on the end. And finally, the G2 Filter last a wider leg span as compared to the Recovery Filter. 03:54PM

Q. Let's talk about that wider leg span.

Page 2, please. 03:55PM

Does this image reflect the increased leg span between the Recovery and the G2?

A. Yes, it does.

Q. And it shows that the Recovery had a leg span of 32 millimeters and you increased that to 40 millimeters which was approximately 25 percent. Right? 03:55PM

A. That is correct.

Q. Would you go to the next page, please.

And this page you talked about the hooks a minute ago. Would you explain the change between the Recovery Filter and 03:55PM

the G2 Filter as to the hooks?
A. So the Recovery Filter hooks were 8.5 thousandths of an inch thick, and the thickness was increased to 10.5 thousandths of an inch on the G2 Filter to make them stronger.
Q. Would you go to the next page, please. 03:55PM
This page seems to highlight the top or the apex of the filter. Would you explain to the jury what this page shows as far as the differences between the Recovery and the G2?
A. So the Recovery Filter in the neck area when you see where the wire exits the tip, and then it takes a turn. There's a 03:56PM relatively small radius of curvature. And on the G2 Filter that radius of curvature was significantly increased to better distribute the loads that are put on the filter.
Q. And was the change to the curvature of the arms coming out of the apex intended to improve fracture resistance in that 03:56PM area of the filter?
A. That is correct.
Q. But that style change alone is not overall responsible for the improved fracture resistance, is it?
A. No it is not. It's just a part of it. 03:56PM
Q. What other changes between the Recovery and the G2 attributed to improved fracture resistance between the Recovery and the G2?
A. So one change was the curved arm and switch would prevent the arms to engage readily into -- sometimes the Recovery 03:57PM

Filter arms would engage in, for example, side vessels, so that was done so the arms wouldn't engage as readily. And the second thing was increased thickness of the hooks which then would provide a more fracture resistance to this part of the filter. 03:57PM

Q. Once you made these design changes -- you can take it down -- between the Recovery and the G2 and you developed the G2 Filter, did you do fatigue testing on it?

A. Yes, we did.

Q. And was that one of hundreds of tests performed on the G2? 03:57PM

A. Yes.

Q. And again, late in the day. I'm not going to go through hundreds of tests. But I do want to talk to you briefly about fatigue testing for the G2.

MS. HELM: Would you please pull you up 5303. 03:58PM

BY MS. HELM:

Q. Do you recognize this document, Mr. Chanduszko?

We've got the wrong number. We'll go without the document.

Did you do fatigue testing on the G2 Filter? 03:58PM

A. So I don't know if I did it personally, but as a team, yes.

Q. I'm sorry?

A. As a team, yes.

Q. Okay. And you mentioned earlier that improved fracture resistance was one of the goals of the G2 Filter, is that 03:58PM

right?
A. Yes. That was one of the main goals.
Q. And did you personally, you, Mr. Chanduszko, create a test to compare the G2 to the Recovery Filter to see if the fracture resistance was improved? 03:58PM
A. Yes. I was the main contributor.
Q. Tell us briefly about that test. What were the test parameters based on?
A. So I mentioned earlier the fatigue test on the Recovery Filter that was tested the filter to one millimeter. This test 03:59PM looked at much more severe deformations, and it was a comparative test, so that the requirement of the project was to make the Recovery Filter more fatigue resistant.

So we had to test the G2 Filter to make sure that it is indeed much more resistant to fatigue than the Recovery 03:59PM Filter.

So in this test, the filter was set up in a special fixture, and the arms of the filter, there were actually multiple filters, would be performed up and down, I believe, about 10 millimeters and they were cycled to the point of 03:59PM fracture. And it was the same test done on Recovery Filter, many of them, and it was the same test done on the G2 filters and then the results were compared.

MS. HELM: Would you please pull up 5303.
BY MS. HELM: 04:00PM

Q. Is this the test report for that testing you just described to the jury?
A. So I think it is, just looking at the cover.
MS. HELM: Would you, Scott, turn to page -- I'm sorry -- 18. 04:00PM
BY MS. HELM:
Q. Mr. Chanduszko, do you see Section 7.11 there?
A. Yes, I do.
Q. And does that refresh your recollection that these are the test results for the test that you just described to the jury? 04:00PM
A. Yes, it does.
MS. HELM: Your Honor at this time I would move for the admission of Exhibit 5303.
THE COURTROOM DEPUTY: I show it in.
MS. HELM: Already in? May I publish, Your Honor. 04:01PM
THE COURT: Let me confirm that. Not that I'm doubting you, Traci. Yeah, it's previously admitted.
Yes, you may.
BY MS. HELM:
Q. Mr. Chanduszko, there in Section 7.11, are those the test results for the test you just described to the jury? 04:01PM
A. Yes, they are.
Q. And do these test results show that the G2 is more fracture resistant than the Recovery Filter?
A. Yes. On the loading conditions actually very 04:01PM

significantly.
Q. Did Bard also do a finite element analysis on the G2 for fatigue in addition to this testing?
A. Yes, we did.
Q. What is the purpose of finite element analysis? 04:01PM
A. So finite element analysis, or FEA, is a computer simulation. In that simulation we typically create a model of the filter and then we can subject it to different deformations and then we can measure the strains and stresses that are produced in the filter. 04:02PM
Q. So you did testing. You saw that you did your testing that you described that showed that the fatigue resistance was better than the Recovery Filter. And then you took the testing information and you did finite element analysis to further analyze it. Is that right? 04:02PM
MR. STOLLER: Objection leading.
THE COURT: Sustained.
BY MS. HELM:
Q. What did you do with the test data from the original test as far as using it in the finite element analysis? 04:02PM
A. So the finite element analysis test was to look at a different loading scenario which was the type that I described earlier for the Recovery Filter.
MS. HELM: Would you please pull up 5037.
BY MS. HELM: 04:03PM

Q. Mr. Chanduszko, do you recognize this document?
A. Yes, I do.
Q. And what is this?
A. So this is a test to evaluate, so it's a computer simulation to evaluate effects of changes to the Recovery Filter in the femoral delivery system and filter stresses based on the FEA analysis. 04:03PM
Q. This is the report of the FEA analysis, right?
A. That's correct.
Q. Are you the originator of this document? 04:03PM
A. Yes, I was.
Q. Is this your report?
A. Yes.
MS. HELM: Your Honor, at this time if it's not already in I move to admit 5037. 04:03PM
MR. STOLLER: No objection.
THE COURT: Admitted.
MS. HELM: May I publish it to the jury?
THE COURT: You may.
MS. HELM: Scott, would you please turn to Page 5, Section 10. 04:03PM
BY MS. HELM:
Q. Mr. Chanduszko, is that the conclusion of the finite element analysis?
A. Yes, it is. 04:04PM

Q. And what did the results of the finite element analysis show about the filter stresses and strengths of the G2 compared to the Recovery Filter?
A. So they show that the modified filter design, which is the G2, showed substantially lower peak stresses compared to the original design which is the Recovery Filter, and it was up to 90 percent. The legs, effect of the results on the legs were similar with 4.6 percent difference in the load configuration, and that was very minimal. 04:04PM
Q. So you did your testing. You can take it down. 04:04PM
You did your finite element analysis. Did you go back and do the original testing that you had done on the Recovery Filter on the G2 again?
A. No, I did not.
Q. Why not? 04:04PM
A. So the answer is, there was no need to do it. And effectively what we had, we had a data from three different tests. So one was the original test on the Recovery Filter. That was ran way past of what the actual standard is. To make sure that the G2 was not -- was more fracture resistant we did 04:05PM the computer simulation to see, mainly, look at the parts that were changed. And the main parts, the main changes that were done were to the neck area and then to the hooks. And both of these areas showed substantial decrease in stress and strain in both compressed for delivery and then expanded configuration in 04:05PM

the vena cava.

Thirdly, we did an actual fatigue test that I described earlier with a much more severe deformation and that test G2 showed very significant improvement over the Recovery Filter. So we had enough evidence to conclude that the G2 Filter was significantly more fracture resistant than the Recovery Filter. 04:06PM

Q. And we focused our discussion on fatigue and fracture resistance. Were there also other tests run on the G2, for example, for cranial migration and tensile strength? 04:06PM

A. Yes. There were many different other tests.

Q. Hundreds, right?

A. So maybe not hundreds times but the tests themselves, yes, they were run many, many times for hundreds and hundreds of filters. 04:06PM

Q. Was there also animal testing done on the G2 Filter?

A. Yes. That's correct.

Q. After your work on the G2 Filter, after it went to market, did you move to a new project or a different project?

A. Yes, I did. 04:07PM

Q. What did you work on after the G2? Do you recall?

A. So after the G2 my recollection is that we started working on G3 which was another generation of vena cava filter.

Q. G3, we haven't heard that one today, or in the last couple of weeks. So before we talk about, and we're going to talk 04:07PM

about it briefly, did the G3 ever go to market?
A. Not in the same form that we started with, no.
Q. And what was the purpose of the G3 project?
A. So my recollection is that it was mainly to improve caudal migration resistance. 04:07PM
Q. So you had the G2 which you had proven through your testing was an improvement over the Recovery Filter, and now you were looking at this G3 project to address caudal migration. Anything else, or was it predominantly a project to address caudal migration? 04:08PM
A. So the caudal migration was the major goal, but obviously in the process of designing, we aim to improve any filter performance characteristic there is.
Q. And as a part of the project to develop the G3 Filter, did you have to develop new test methods and do additional testing to address caudal migration alone? 04:08PM
A. Yes. In fact, we were developing many different test methods, not just one.
Q. So as the filters progress and as you move through the generation of filters, did Bard continue to develop its test methods and test procedures along with new filters? 04:08PM
A. That's correct. There were over time we developed many different test methods that we added to the requirements for testing.
Q. Based on the information you learned through prior testing 04:08PM

or test results, right?
A. That's correct, or clinical experience, any of the above.
Q. So you are not staying at your Recovery test methods back from when the Recovery was developed as you are continuing to improve and develop new filters over time, are you? 04:09PM
A. Absolutely not.
Q. Okay. So in addition to continually looking to improve your filters, you are also continuing to improve your technology and your testing, right?
MR. STOLLER: Objection. Leading. 04:09PM
THE COURT: Sustained.
BY MS. HELM:
Q. In addition to continuing to improve filters, are you also continuing to improve your technology and your testing?
A. Yes. 04:09PM
Q. Are you also looking to continually improve your knowledge about the filters and how they perform in the inferior vena cava?
A. Absolutely.
Q. Did this G3 -- we talked about the G3 filter. It did not 04:09PM make it to market, is that right?
A. That is correct.
Q. What happened? Why didn't it go to market?
A. So like I said, my recollection is that we were looking to ways to stabilize the filter, particularly, have a better 04:10PM

improvement over G2 from a caudal migration standpoint. But this is not the only consideration like I said. So we went through a number of different prototypes. Typically with the filters, you -- it's not just the implant but you have to design a delivery system to deliver it without any damage. We also added number of different test methods that we had to develop effectively from scratch. 04:10PM

So in the end we developed three or four different prototypes and these prototypes were tested in animals. Unfortunately we cannot replicate every clinical characteristic on the bench. So often times the animal is effectively the last test where we pretty much test everything because that's the most similar to the human anatomy. And what we found is that we had some filters that had significant penetrations and there were others that were marginal. So at that point we decided that this design is not going to work, and effectively, we scratched it and we went back to the drawing board. 04:10PM 04:11PM

Q. How long did you work on the G3 project before you tabled it and went back to the drawing board?

A. I think about two years. 04:11PM

Q. And what was the next project you worked on after the G3?

A. So it was a project that we called Platinum.

Q. And did that project go to market?

A. That project did not go to market either, at least not the way it was started. 04:12PM

Q. Did you also work on the Denali Filter?
A. Yes, I did.
Q. And the jury's heard briefly about the Denali Filter. Do you recall what year the Denali Filter went to market?
A. When? 04:12PM
Q. Do you recall what year the Denali Filter went to market?
A. I believe it was 2013.
Q. And how long did you work on the Denali Filter before it went to market?
A. Probably about five years. 04:12PM
Q. Okay.
A. Or maybe, I should say, the team. So the total project length was about that.
Q. And during that five-year time period, the Denali Filter is a different filter. It's designed differently than the G2 or 04:12PM the Eclipse, is that right?
MR. STOLLER: Objection leading.
THE COURT: Sustained.
BY MS. HELM:
Q. Is the Denali designed differently than the G2 or the 04:13PM Eclipse?
A. It's largely different in some respects and similar, but it's largely different, yes.
Q. While you were working on the Denali did you also have the opportunity to do some work on the Eclipse Filter? 04:13PM

A. To -- could you repeat, please?
Q. Sure. Are you familiar with the Eclipse Filter?
A. Yes, I am.
Q. Did you do any work on the Eclipse Filter?
A. To some minimal degree, but yes, I'm familiar with what the team did on that project. 04:13PM
Q. What is the difference between the Eclipse Filter and the G11 or the G2X Filter?
A. So the difference is that the Eclipse is an electropolished filter and the G2X is not that's the only difference. 04:13PM
Q. What are the possible general risks or problems that could happen with electropolishing a filter made out of Nitinol?
A. So general risks could be hydrogen I'm brittle. Which would lead to the material being brittle. It could be dimensional inconsistency, meaning the dimensions may not be controlled to the degree that is needed for this device. It could be pits, it could be other surface damage. 04:14PM
Q. Did it take Bard some time to perfect the ability to electropolish the filter which became the Eclipse Filter before it put it on the market? 04:14PM
A. So we did not have the expertise in house to do this kind of operation so we worked with external experts that, you know, for example, Nitinol producers, and they worked on the project and it took us several years to effectively get this project to the point where it could be usable for this device. 04:15PM

Q. And did Bard wait until it was comfortable that it had perfected the electropolishing before it put the Eclipse on the market?
A. Yes. Absolutely.
Q. Do you believe that electropolishing the Eclipse Filter may improve the fatigue or fracture resistance of the filter? 04:15PM
A. So not only I believe, but we have a test data that clearly shows that.
Q. Were the changes, the electropolishing, the changes that were made from the G2 or the G2X to the Eclipse, intended to make it an improvement? 04:15PM
A. Yes. Of course.
Q. Even though Bard has later developed filters and continued to make changes to filters, do you believe that the Eclipse Filter was a safe filter? 04:16PM
A. Yes.
Q. Mr. Chanduszko when you graduated with a degree in mechanical engineering, aside from the medical device field what other fields could you have worked in?
A. Pretty much everything. I could be making Ramen noodles or space shuttles. 04:16PM
Q. Cars? Ladders?
A. Anything.
Q. Why have you chosen to devote your entire professional career to working with medical devices such as IVC filters? 04:16PM

A. So I was, and still am, very passionate about it. It goes back to my experience at Mass General Hospital. And I worked there for a number of years and I have seen human suffering. So I really wanted to help.

Q. Do sales or profits of the company drive your decision making process when you are designing an IVC filter? 04:16PM

A. No, they don't.

Q. What drives your decision making process?

A. To make the best product possible to help patients.

Q. Thank you. No further questions. 04:17PM

THE COURT: Cross-examination?

MR. STOLLER: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. STOLLER:

Q. Mr. Chanduszko, my name is Paul Stoller. We have not met before. Good afternoon. 04:17PM

A. Good afternoon.

Q. I'd like to ask you some questions about the role of an engineer in a medical device company. And you testified a bit about that earlier this afternoon. 04:17PM

Would you agree with me that one of your jobs as an engineer is to design and test products to ensure that they are safe in the human body or at least as safe as they can reasonably be?

A. Yes. That's correct. 04:18PM

Q. And would you agree that in doing that you need to consider the worst-case scenario or the reasonable worst-case scenario that those filters or products may experience in the body?
A. Yes.
Q. And I believe when Ms. Helm was asking you questions earlier, she asked you about the purposes of bench testing and I think you said that you have to understand the environment because it may challenge filters in all kinds if different ways. Did I hear that correctly? 04:18PM
A. Yes. I believe so. 04:18PM
Q. And so one of the things you want to do when you are bench testing is try to simulate the real world as closely as possible so that you can understand the challenges that a filter is going to place while it's in the body. Is that fair?
A. Generally speaking, yes. 04:19PM
Q. And when you were testing filters here, one of the things you needed to keep in mind were those challenges that the filter might face in the body that could cause failures. True?
A. One of the things, yes.
Q. So let's talk about some of the tests that you ran. 04:19PM
And I think that you indicated one of the tests that you ran for -- and I will start chronologically like Ms. Helm did, with the fatigue test report you ran for the Recovery Filter, which I believe was Exhibit 5234. I'm not going to put it up because I don't want to talk about the specifics of it. 04:19PM

But I want to ask you some general questions about that test.

I believe your testimony was that in that test, what you did was you took the filter and you squeezed it one millimeter. Is that correct?

A. So the requirement for the test -- so what the test was supposed to simulate is the deformations that the filter would experience during breathing. And the requirement was one millimeters minimal distension. The test that we ran was actually higher than that, and I believe it was anywhere from one millimeter to about 1.7 millimeters. 04:19PM 04:20PM

Q. And I'm going to -- we're short on time so I'm going to try and ask mostly yes or no questions. If you can't answer yes or no let me know and I will try to clarify. Is that all right?

A. Yes.

Q. And I'm going to talk a little quickly but apologize to everybody for that as we go. 04:20PM

But the compression you did there was you took a filter and you squeezed it, and you just said somewhere between a millimeter and 1.7 millimeters, correct?

A. Yes. That's correct. 04:20PM

Q. And the idea of that was to simulate normal human breathing, correct?

A. Yes.

Q. And you ran that test, you said originally set out to 32 million cycles and then to 36, correct? 04:21PM

A. So the goal was 32 and the test was stopped at 36 is my recollection.
Q. And then you said you even ran it out longer than that for a long period of time. True?
A. 400 million cycles. 04:21PM
Q. And your conclusion on that was when it faced normal human breathing, the filter didn't break over the course of how many ever cycles you ran it. True?
A. Correct.
Q. So, sir, what worst-case condition for breathing testing 04:21PM did you do in the bench to demonstrate that the filter wouldn't break when it faced worst-case conditions?
A. So this one actually I could argue is the worst-case because we're all breathing so this is very common. I will consider that a worst-case. That's one way to look at it. The 04:21PM other also is that the requirement was one millimeter. That's where we had the clinical input but we ran at it at much higher deformations and then we ran it for a much more extended number of cycles, which was actually equivalent to way over 50 years.
Q. Sir, your testimony was this was to mimic normal breathing. 04:22PM True?
A. That's correct.
Q. And you know that the IVC expands and contracts a lot more in all kinds of situations than it does in normal breathing. True? 04:22PM

A. IVC alone it may, yes. But it would be at a much lower frequency.
Q. Sir, I'm going to ask you yes or no questions. If you can't answer them yes or no, please tell me and I will ask you a different question. Is that fair? 04:22PM
A. I will do my best.
Q. Okay. So you were trying to simulate normal human breathing. True?
A. Yes.
Q. And you ran it out for some million number of cycles by 04:22PM squeezing it a millimeter to 1.7 millimeters. True?
A. Yes.
Q. And you knew and you know now that the IVC twists, turns, we have seen it and the jury's seen it, compresses, expands much more than 1 to 1.7 millimeters. True? 04:23PM
A. The IVC without a filter, yes.
Q. You don't know what the effect of the -- I'm not -- the answer to my question is true, isn't it?
A. Yes.
Q. And you did not perform simulations of twisting, turning, 04:23PM compressing, expanding beyond 1.7 millimeters. True?
A. For the Recovery Filter, yes. That's true.
Q. So let's talk about -- and that passed that test in your mind. Correct?
A. Not just in my mind but it did pass. Yes. 04:23PM

Q. Then you said you made some pretty significant changes to the -- from the G2 -- I'm sorry -- from the Recovery to the G2, correct?
A. Correct.
MR. STOLLER: And I don't have it, but could we pull up -- I beg your indulgence -- 7875. 04:24PM
May we display this to the jury, Your Honor?
THE COURT: This is the demonstrative?
MR. STOLLER: Yes. This is the defense demonstrative.
THE COURT: You may. 04:24PM
MR. STOLLER: Thank you.
BY MR. STOLLER:
Q. Mr. Chanduszko, this is the demonstrative you created with Ms. Helm to show the differences in the Recovery and the G2. Correct? 04:24PM
A. I don't know if I created it but I described it.
Q. Fair enough. And this shows a number of differences in moving from the Recovery to the G2, does it not?
A. Yes, it does.
Q. You widened the legs pretty substantially, right? 04:24PM
A. Correct.
Q. And when I look at these side by side, that's a very big difference in the leg span. Would you agree with that?
A. Yes, I would.
Q. You also said that you changed the hooks, made them 04:24PM

stronger. Correct?
A. Correct.
Q. You changed -- you lengthened the arms, correct?
A. Correct.
Q. You changed the angle of the arms, correct? 04:25PM
A. I don't know if the angle is changed, but no, I think the angle is roughly the same.
Q. I meant at the top. At the top of where it is in the filter, you changed that. Correct?
A. Yes, the neck. 04:25PM
Q. And I think you also testified this response to some things Ms. Helm asked you that when you make one change to try to address a complication in the device sometimes it has an effect of creating other complications. True?
A. It might, yes. 04:25PM
Q. And one of the things that you needed to look at or should have been looking at when you made pretty significant changes from the Recovery to the G2 was to determine whether in trying to address migration and widening the leg span of the filter it created other complications. Shouldn't you have been doing 04:25PM that?
A. Yes.
Q. So let me ask you, sir, what testing you did for the G2 to ensure that the change in the filter design -- let me change the question. 04:26PM

When you changed the filter design from the Recovery to the G2 and you significantly widened the base, you did not test to see what effect that would have on the filter's propensity to tilt, did you?
A. We did, absolutely. 04:26PM
Q. You ran bench tests to see that this would not cause further tilt?
A. Yes. Multiple ones.
Q. And where are those, sir?
A. They will be in lab notebooks. There will be in reports. 04:26PM
Q. Were they listed in the DV&V you did for the FDA for testing purposes?
A. DV&V will have testing, yes.
Q. I'm asking about this particular test, sir. Do you know?
A. One of the tests, yes, I'm sure. There's multiple tests 04:26PM actually that takes that into account.
Q. That's not my question, sir. My question was: Did that test that you claimed to have performed to measure the result of the widened base of the G2 Filter, causing its propensity to tilt, is that included in the DV&V report that was provided to 04:27PM the FDA?
A. So I can think of at least of one test that looked at that. But every single test effectively takes that into account.
Q. Your testimony, sir, is every single test looked at whether or not this change caused the filter to tilt? 04:27PM

A. Most of them would look at that particular characteristic, yes.

Q. Let's move on then, sir, and the jury will look at the DV&V when it has the opportunity in the jury room.

You testified earlier in response to Ms. Helm's questions that you performed other tests to measure the fracture resistance in the G2 Filter as a result of the changes that were made. 04:27PM

Did I understand that correctly?

A. We performed two tests, at least from what I remember. 04:28PM

Q. And you did not -- the tests that you performed on the Recovery you did not perform on the G2, correct?

Let me be clear, because that's not fair. There were a number of tests you performed.

The tests we just talked about, the compression tests to simulate breathing, you did not perform that test on the G2, did you? 04:28PM

A. We did not. That's correct.

Q. And you performed -- you said you developed another test to test, I believe your terms were different loading conditions. Correct? 04:28PM

A. Yes. There was an FEA analysis and there was another test which looks at the more severe deformations.

Q. Let me talk about the latter which is the bench test you created. And the jury has heard about this and the jury heard 04:28PM

it referred to as the saluting arm test. Have you referred to that test as the saluting arm test?
A. We typically call it the arm fatigue test, but yes. That would be another way to describe.
Q. That's a test where you take the filter arms, move them up on up and down and up and down until they break, correct? 04:29PM
A. Yes.
Q. And you performed that test and concluded that the G2 was better at that test than the Recovery had been, correct?
A. That's correct. 04:29PM
Q. Now, sir, one of the issues coming out of that test was you did not conduct an FEA or finite element analysis of that same test to see what the results would be, did you?
A. I don't think we did, and I don't think there was a need for that. 04:29PM
THE COURT: We're going to stop at this point, Mr. Stoller.
Ladies and Gentlemen, we'll plan to begin at 9 in the morning and we will excuse you for the evening. Thank you.
MR. STOLLER: Thank you, Your Honor. 04:29PM
(Jury out at 4:29 p.m.)
THE COURT: I'm going to give you your time, counsel, if you hold on for just a minute.
All right, counsel. As of now, plaintiff has used 23 hours, 51 minutes. Defendants have used 11 hours, 37 minutes. 04:31PM

And we will plan to see you at 8:30.

Please remember tomorrow at this time we're going to talk about the jury instructions.

See you tomorrow.

MR. LOPEZ: Do we let the jury go at 4? 04:32PM

THE COURT: Let me tell you that in the morning. I want to see how we're doing on our overall schedule in meeting the time. If we can let them go at 4 tomorrow, they would probably appreciate it. That would give us a little more time for jury instructions. I will see if that works with getting 04:32PM the trial done in time.

MS. HELM: Thank you, Your Honor.

(Proceeding recessed at 4:32 p.m.)

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 25th day of May, 2018.

s/Laurie A. Adams
_____
Laurie A. Adams, RMR, CRR